EXHIBIT BA

PROGRAM MEMORANDUM
INTERMEDIARIES/CARRIERS

Department of Health and Human Services

Health Care Financing Administration

Transmittal No. AB-98-76 Date DECEMBER 1998

CHANGE REQUEST #745

SUBJECT: Implementation of the New Payment Limit for Drugs and Biologicals

The purpose of this program memorandum (PM) is to furnish you with instructions needed to implement the Code of Federal Regulations (CFR), 42 CFR 405.517, as amended in the Federal Register (FR) in 63 FR 58849. This section of the regulations specifies that drugs and biologicals be paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as described below.

Payments for Drugs and Biologicals

Drugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the Red Book, Blue Book, or Medispan. Examples of drugs that are paid on this basis are drugs furnished incident to a physician's service, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anti-cancer drugs, and drugs furnished by independent dialysis facilities that are not included in the end stage renal disease composite rate payment.

Currently, the AWP of a drug or biological is determined by the methodology described in PM AB 97-25 dated January 1998. Effective with your next scheduled drug payment update, but no later than April 1, 1999, determine the AWP as described below.

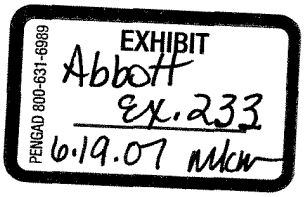
Calculation of the AWP

1. For a single-source drug or biological, the AWP equals the AWP of the single product.

2. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP. A "brand name" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

3. After determining the AWP, multiply it by 0.95. This is the new drug payment allowance limit. Do not round this payment allowance limit. There is no minimum for this amount.

Intermediary Processed Claims



The procedure for processing intermediary claims has not changed. As described in PM AB 97-25, all carriers will continue to furnish their drug payment allowance updates for all drugs and biologicals directly to the fiscal intermediaries in their jurisdiction free of charge.

Carriers should contact the fiscal intermediaries to determine the preferred method of transmission. Carriers are to send this information to all fiscal intermediaries they routinely deal with. If this method of obtaining payment allowance updates does not work for any intermediary, contact your appropriate regional office immediately.

These instructions replace the current payment calculation instructions in PM AB-97-25; §5202 of the Medicare Carriers Manual, Part 3; §3644.E of the Medicare Intermediary Manual, Part 3; §2711.2.B.2 of the Provider Reimbursement Manual, Part 1, Chapter 27; and §319.1 of the Renal Dialysis Facility Manual. Manual revisions will be issued soon.

These instructions should be implemented within your current operating budget.

This PM may be discarded August 31, 1999.

Contact Person: Robert Niemann on (410)786-4569.

 Return To Program Memos

 Return to Program Manuals

Last Updated January 20, 1999

EXHIBIT BB

TO: Kevin Thurm
Deputy Secretary
COS _____
ES _____

FR: Michael M. Hash
Deputy Administrator

RE: Medicare Payments for Drugs Using Department of Justice Data -- INFORMATION

The Health Care Financing Administration (HCFA) is moving ahead to implement revisions to Medicare payments for drugs by using new average wholesale price data compiled by the Department of Justice (DOJ). The purpose of this memo is to update you regarding our progress.

Background

By law, Medicare payment is based either on the lower of the billed charge or 95 percent of the average wholesale price (AWP). Medicare contractors obtain the AWP data from one of several sources, primarily the *Red Book*. For years, many analysts have believed that the drug manufacturers have artificially inflated the AWP data. In fact, earlier this year, DOJ compiled a new set of AWPs for 51 drugs as part of a lawsuit. In May 2000, these data were made available to State Medicaid programs, some of which have implemented them while others have not.

Following several inquiries from Congress, the Secretary announced in a letter to Congressman Bliley that HCFA would provide our contractors the DOJ data. The HCFA Administrator wrote a similar letter to Congressman Stark (attached). More specifically, the Secretary's letter indicated that HCFA, by the end of June, would send the DOJ data to carriers for them to use for their next quarterly update of Medicare drug allowances which will become effective October 1, 2000. We also indicated that we could not require carriers to use these new data. Finally, in an effort to ensure access and quality, the letter stated that HCFA would meet with physician groups to review the adequacy of the reduced payment rates for chemotherapy administration.

Actions Taken

HCFA met with oncology physicians. 14 of the 51 drugs on the DOJ list are oncology drugs. Oncology physicians indicate that drug mark-ups compensate for what they believe are inadequate Medicare payments for chemotherapy administration. About 67 percent of oncologists' Medicare revenues are from drugs and implementation of the DOJ data would result in a 7 percent reduction in their Medicare revenues. Therefore, we are reviewing our payment policies (e.g., payment for multiple "pushes" on the same day) for chemotherapy administration. However, any policy changes could not be implemented before January 1, 2001 (through the physician fee schedule final rule). Based on further analysis, ~~it is unclear that~~ these drugs represent about 17 percent of Medicare spending for drugs on the DOJ list and 26 percent of the savings. The reimbursement reductions for oncology drugs would average 75 percent. (Please see attached chart.)

REDACTED

We have already received letters from physicians and cancer patients that use of the DOJ data would limit access to cancer care and cause physicians to send patients to hospital outpatient departments for treatment. We believe that REDACTED

Similarly, we have met with a hemophilia supplier. We believe that their views reflect the views of the larger industry. Hemophilia drugs are furnished by suppliers to patients either in their home or through hemophilia centers. Medicare does not make payments to hemophilia centers or for suppliers to furnish drugs to home patients. As a result, suppliers use drug mark-ups to cover these costs. Suppliers argue that they will not be able to furnish services to Medicare patients if the DOJ data are implemented. The reduction for hemophilia drugs is about 30 percent. The three hemophilia drugs on the DOJ list represent about 5 percent of Medicare spending for drugs on the list and about 5 percent of the savings.

We have also analyzed the other drugs. Of the remaining 34 drugs, 2 are furnished by urologists (the largest being lupron), 4 are inhalation drugs furnished by durable medical equipment suppliers (the largest being albuterol), 2 are end-stage renal disease drugs (other than EPO) and 20 drugs are steroids, tranquilizers, antibiotics, impotence-related, AIDS-related, etc. 2 of the 51 drugs are not covered under the Medicare drug benefit (and thus not paid under the average wholesale price) and another 4 have no Medicare billing codes.

Finally, we also have received a revised opinion from OGC indicating that HCFA can require carriers to use the DOJ data, even without rule making. This is because the data is characterized by DOJ as more accurately reflecting average wholesale prices.

Next Steps

REDACTED

Attachment: DOJ Drug List by Category

Category	CY 1999 Data Medicare Spending	Savings from DOJ
Oncology	$298,218,671 17.1%	($168,972,413) 26.4%
Hemophilia	$93,584,360 5.4%	($29,659,941) 4.6%
Inhalation	$288,396,256 16.5%	($190,203,823) 29.7%
Urology	$637,157,314 36.6%	($132,072,913) 20.6%
ESRD	$306,404,809 17.6%	($82,503,176) 12.9%
Misc	$119,464,591 6.9%	($36,283,616) 5.7%
	$1,743,226,002	($639,695,882)

EXHIBIT BC

U.S. Department of Justice

Civil Division, Fraud Section

601 D Street, NW
Washington, D.C. 20004

Telephone: (202) 305-9300
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Via Electronic Transmission

March 13, 2009

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Re: Average Wholesale Price Multi-District Litigation
MDL No. 1456/C.A. No. 01-12257-PBS (D. Mass.)

Dear Counsel:

I am writing in response to separate letters from Messrs. Torborg and Cook dated February 19, 2009 as well as to questions from defense counsel regarding the Government's document productions on December 15, 2008 and January 27, 2009 - which for the most part consisted of materials relating to Medicaid state plan amendments.

As a part of the Government's response to defendants' requests for production, CMS' regional offices had been instructed to produce all state plan amendments. In addition to the state plan amendments themselves, the regions were also asked to produce files which contained notes, e-mails, letters, and other documentation surrounding the approval or disapproval of state plan amendments. All of the regional offices responded and that material, in excess of 20,000 pages, was produced to defendants over the course of discovery. Additionally, state plan material was produced to defendants as a part of the Government's Rule 26 Initial Disclosures.

The state plan amendment files which are located in CMS' central office in Baltimore in were initially presumed to be duplicates of the files produced by the regional offices. Moreover, CMS's central office did not take over the review of the state plans until May 2002. As we worked to assess the extent to which the CMS central office files were duplicates of what had already been produced, it appeared that at least some of the documents had not been previously produced. Accordingly, we sped up our effort to process and produce the central office state plan files by December 15. While the material produced on the 15th was placed on twenty-five compact discs, we estimate that the volume of the material produced amounts to roughly four boxes of documents.

As a part of our expedited review efforts, some material was set aside for additional

review by CMS' Office of General Counsel (OGC). A portion of this material was reviewed and produced on January 27, 2009, but incorrectly described as having been released from a privilege log. In fact, the Government had never claimed privilege for the documents that were produced to defendants on January 27. Among the material set aside was information pertaining to Illinois state plan amendment 02-09. Included in this file was the email thread between CMS's Kimberly Howell and an employee of the Illinois Department of Public Aid referenced in Mr. Toborg's letter of February 19, 2009. That material is currently with our contractor and we expect to produce it shortly, probably next week.

Mr. Cook has inquired about an OGC opinion concerning whether CMS could use an alternate source of AWPs to determine payment amounts for drugs. As we previously advised Mr. Cook, we have been unable to locate any OGC document containing this opinion and, based on our inquiries, now believe that the referenced opinion was conveyed orally by OGC staff.

Thank you for your attention.

Very Truly Yours,

/s/
Justin Draycott
Trial Attorney
Commercial Litigation Branch

cc: George B. Henderson
Jim Breen

EXHIBIT BD

Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-01-66 **Date: MAY 3, 2001**

CHANGE REQUEST 1653

SUBJECT: Implementation of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) Requirements for Payment Allowance of Drugs and Biologicals Covered by Medicare

The purpose of this Program Memorandum (PM) is to provide implementing instructions for PM AB-01-16, Change Request 1514 with respect to the requirements in §429(c) of the BIPA. Section 429 requires the General Accounting Office (GAO) to study and report to Congress and the Secretary of the Department of Health and Human Services on the reimbursement for drugs and biologicals under Medicare, including specific recommendations for revised payment methodologies. Section 429 also provides a moratorium on decreasing the payment rates in effect as of January 1, 2001, for drugs and biologicals under the current Medicare payment methodology. The moratorium applies until HCFA has reviewed the GAO report. See the discussion below for a description of the scope of this moratorium.

Scope of Moratorium

The moratorium imposes a prohibition against lowering the payment allowance based on a change in methodology. Under certain circumstances, following the established methodology (see PMs AB-00-110, Change Request 745, and AB-00-115, Change Request 1447) and using a carrier's usual source of Average Wholesale Price (AWP) may lead to a lower payment allowance for a particular product. For example, if the payment allowance for a drug was based on 95 percent of the AWP for a single-source brand name product, and a new generic form of the product became available at a lower AWP, then following PM AB-00-110 would result in a new, lower payment allowance based on 95 percent of the AWP of the lower priced generic form. This is appropriate. Another example is if a drug manufacturer lowers its AWP for a product as reflected in a subsequent issue of the carrier's usual source of AWP. However carriers may not reduce the payment allowance from 95 percent of the AWP to, for example, 90 percent of the AWP. Nor may carriers use an alternative source for average wholesale prices.

Instructions

Continue to follow the rules in PMs AB-00-110 and AB-00-115. Use the established methodology in AB-00-110 for determining the payment allowances for drugs and biologicals. Also, per PM AB-00-115 use your usual source for AWP. Do not use any alternative sources of data for average wholesale prices for these items.

The *effective date* for this PM is for items furnished on or after January 1, 2001.

The *implementation date* for this PM is May 3, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after June 30, 2002.

If you have any questions, contact Robert Niemann at (410) 786-4531.

HCFA - Pub. 60AB

EXHIBIT BE

42 U.S.C.A. § 1395u

Effective: December 08, 2003 to December 31, 2004

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security
Subchapter XVIII. Health Insurance for Aged and Disabled
Part B. Supplementary Medical Insurance Benefits for Aged and Disabled

➞§ 1395u. Use of carriers for administration of benefits

(a) Authority of Secretary to enter into contracts with carriers

In order to provide for the administration of the benefits under this part with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A of this subchapter and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1395h of this title are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

(B) receive, disburse, and account for funds in making such payments; and

(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part;

(2)(A) determine compliance with the requirements of section 1395x(k) of this title as to utilization review; and

(B) assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1395x(k)(2) of this title) to make reviews of utilization;

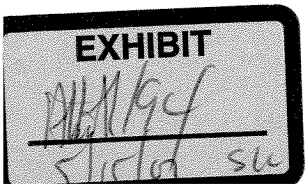
(3) serve as a channel of communication of information relating to the administration of this part; and

(4) otherwise assist, in such manner as the contract may provide, in discharging administrative duties necessary to carry out the purposes of this part.

(b) Applicability of competitive bidding provisions; findings as to financial responsibility, etc., of carrier; contractual duties imposed by contract

(1) Contracts with carriers under subsection (a) of this section may be entered into without regard to section 5 of Title 41 or any other provision of law requiring competitive bidding.

(2)(A) No such contract shall be entered into with any carrier unless the Secretary finds that such carrier will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial



responsibility, legal authority, and other matters as he finds pertinent. The Secretary shall publish in the Federal Register standards and criteria for the efficient and effective performance of contract obligations under this section, and opportunity shall be provided for public comment prior to implementation. In establishing such standards and criteria, the Secretary shall provide a system to measure a carrier's performance of responsibilities described in paragraph (3)(H), subsection (h) of this section, and section 1395w-1(e)(2) of this title. The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1395hh of this title, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1395y(b) of this title may apply.

(B) The Secretary shall establish standards for evaluating carriers' performance of reviews of initial carrier determinations and of fair hearings under paragraph (3)(C), under which a carrier is expected--

(i) to complete such reviews, within 45 days after the date of a request by an individual enrolled under this part for such a review, in 95 percent of such requests, and

(ii) to make a final determination, within 120 days after the date of receipt of a request by an individual enrolled under this part for a fair hearing under paragraph (3)(C), in 90 percent of such cases.

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1395x(s)(2)(K) of this title performed by a member of a team, the Secretary shall instruct carriers to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

(D) In addition to any other standards and criteria established by the Secretary for evaluating carrier performance under this paragraph relating to avoiding erroneous payments, the carrier shall be subject to standards and criteria relating to the carrier's success in recovering payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1395y(b)(2)(A) of this title).

(E) With respect to the payment of claims for home health services under this part that, but for the amendments made by section 4611 of the Balanced Budget Act of 1997, would be payable under part A of this subchapter instead of under this part, the Secretary shall continue administration of such claims through fiscal intermediaries under section 1395h of this title.

(3) Each such contract shall provide that the carrier--

(A) will take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1395x(v) of this title);

(B) will take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier, and such payment will (except as otherwise provided in section 1395gg(f) of this title) be made--

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this subchapter is denied under section 1320c-3(a)(2) of this title by reason of a determination under section 1320c-3(a)(1)(B) of this title, and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1395y(a) of this title, and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual;

except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter (except in the case of physicians' services and ambulance service furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title);

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year);

(C) will establish and maintain procedures pursuant to which an individual enrolled under this part will be granted an opportunity for a fair hearing by the carrier, in any case where the amount in controversy is at least $100, but less than $500, when requests for payment under this part with respect to services furnished him are denied or are not acted upon with reasonable promptness or when the amount of such payment is in controversy;

(D) will furnish to the Secretary such timely information and reports as he may find necessary in performing his functions under this part;

(E) will maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (D) and otherwise to carry out the purposes of this part;

(F) will take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) will, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1395w-4(g) of this title--

(i) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1395w-4(g)(2) of this title;

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) if it makes determinations or payments with respect to physicians' services, will implement--

(i) programs to recruit and retain physicians as participating physicians in the area served by the carrier, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;

(I) will submit annual reports to the Secretary describing the steps taken to recover payments made under this part for items or services for which payment has been or could be made under a primary plan (as defined in section 1395y(b)(2)(A) of this title); and

(J), (K) Repealed. Pub.L. 101-234, Title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981

42 U.S.C.A. § 1395u

(L) will monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality;

and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate. In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1395x(s)(6) of this title, charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, or agent of the Department of Health and Human Services performing functions under this subchapter and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1395x(v)(1)(K) of this title, and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii)(I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8- month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as

defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a nonparticipating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 3- month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4) of this section) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3) of this section) for each year shall be the same for nonparticipating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services--

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12- month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4) of this section) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1) of this section) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a nonparticipating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C) of this section.

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is--

(I) 3.6 percent for primary care services (as defined in subsection (i)(4) of this section), and

(II) 1 percent for other physicians' services.

(iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is--

(I) 3.0 percent for primary care services, and

(II) 1 percent for other physicians' services.

(iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is--

(I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)) of this section.

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(v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is--

(I) 0 percent for services (other than primary care services), and

(II) 2 percent for primary care services (as defined in subsection (i)(4) of this section).

(5) Each contract under this section shall be for a term of at least one year, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that the Secretary may terminate any such contract at any time (after such reasonable notice and opportunity for hearing to the carrier involved as he may provide in regulations) if he finds that the carrier has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the insurance program established by this part.

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1395gg of this title) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part, (C) in the case of services described in clause (i) of section 1395x(s)(2)(K) of this title, payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1395x(aa)(2) of this title) for a continuous period beginning prior to August 5, 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1395x(aa)(2) of this title, payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days; and (iv) the claim form submitted to the carrier for such services includes the second physician's unique identifier (provided under the system established under subsection (r) of this section) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this subchapter is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed, (E) in the case of an item or service (other than services described in section 1395yy(e)(2)(A)(ii) of this title) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services

(including medical supplies described in section 1395x(m)(5)of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), and (G) in the case of services in a hospital or clinic to which section 1395qq(e) of this title applies, payment shall be made to such hospital or clinic.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, the carrier shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part--

(i) unless--

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this subchapter, and

(III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), the carrier shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, the carrier shall base payment under this subchapter on the greatest of--

(I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),

(II) the meaning of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

(iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.

(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects

payment to be determined under this subparagraph, the carrier shall provide for payment for such services under this part on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

(D)(i) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary--

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term "assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(8)(A)(i) The Secretary shall by regulation--

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this subchapter to payment under this part (other than to physicians' services paid under section 1395w-4 of this title) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if--

(i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this subchapter and subchapter XIX are the sole or primary sources of payment for an item or service.

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(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register--

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987--

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is--

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight-line sliding scale, equal to 3/13 of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges

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for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, subrapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(D) There shall be no administrative or judicial review under section 1395ff of this title or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall--

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1395x(r) of this title), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.

(C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physicians' service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(12) Repealed. Pub.L. 105-33, Title IV, § 4512(b)(2), Aug. 5, 1997, 111 Stat. 444

(13)(A) In determining payments under section 1395l(l) of this title and section 1395w-4 of this title for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of August 10, 1993.

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the

periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(A)(i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, 1/3 of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of--

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

(II) the adjustment factor (specified under clause (iii)) for the locality.

(ii) The "reduced national weighted average prevailing charge" for a physicians' service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.

(iii) The "adjustment factor", for a physicians' service for a locality, is the sum of--

(I) The practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101-M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv) for the locality, and

(II) 1 minus the practice expense component (percent), divided by 100.

(C) For purposes of this paragraph:

(i) The procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specification is of physicians' services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part.

(ii) The "national weighted average prevailing charge" specified in this clause, for a physicians' service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

(iii) The "percentage change" specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs

Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians' services which the Secretary shall designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(16)(A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4) of this section, hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; femoral fracture treatments; trochanteric fracture and endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable x-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) of this section in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) of this section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1395x(aa)(5) of this title).

(ii) A certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title).

(iii) A certified nurse-midwife (as defined in section 1395x(gg)(2) of this title).

(iv) A clinical social worker (as defined in section 1395x(hh)(1) of this title).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1395x(ii) of this title).

(vi) A registered dietitian or nutrition professional.

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1395l(a)(1) of this title, the reasonable charge for ambulance services (as described in section 1861(s)(7)) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved reduced by 1.0 percentage point.

(c) Advances of funds to carrier; prompt payment of claims

(1) Any contract entered into with a carrier under this section shall provide for advances of funds to the carrier for the making of payments by it under this part, and shall provide for payment of the cost of administration of the carrier, as determined by the Secretary to be necessary and proper for carrying out the functions covered by the contract. The Secretary shall provide that in determining a carrier's necessary and proper cost of administration, the Secretary shall, with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract. The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for carriers under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.

(2)(A) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B) of this section, shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part--

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

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(ii) The term "applicable number of calendar days" means--

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of Title 31 (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B) of this section, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this subchapter within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term "applicable number of calendar days" means--

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 26 days.

(4) Neither a carrier nor the Secretary may impose a fee under this subchapter--

(A) for the filing of claims related to physicians' services,

(B) for an error in filing a claim relating to physicians' services or for such a claim which is denied,

(C) for any appeal under this subchapter with respect to physicians' services,

(D) for applying for (or obtaining) a unique identifier under subsection (r) of this section, or

(E) for responding to inquiries respecting physicians' services or for providing information with respect to medical review of such services.

(5) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B) of this section, shall require the carrier to meet criteria developed by the Secretary to measure the timeliness of carrier responses to requests for payment of items described in section 1395m(a)(15)(C) of this title.

(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1395ddd of this title. The previous sentence shall not apply with respect to the activity described in section 1395ddd(b)(5) of this title (relating to prior authorization of certain items of durable medical equipment under

section 1395m(a)(15) of this title).

(d) Surety bonds

Any contract with a carrier under this section may require such carrier or any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(e) Liability of certifying or disbursing officers or carriers

(1) No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payments certified by him under this section.

(2) No disbursing officer shall, in the absence of gross negligence or intent to defraud the United States, be liable with respect to any payment by him under this section if it was based upon a voucher signed by a certifying officer designated as provided in paragraph (1) of this subsection.

(3) No such carrier shall be liable to the United States for any payments referred to in paragraph (1) or (2).

(f) "Carrier" defined

For purposes of this part, the term "carrier" means--

(1) with respect to providers of services and other persons, a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization; and

(2) with respect to providers of services only, any agency or organization (not described in paragraph (1)) with which an agreement is in effect under section 1395h of this title.

(g) Authority of Railroad Retirement Board to enter into contracts with carriers

The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a carrier or carriers to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 426(a) of this title and section 231f(d) of Title 45.

(h) Participating physician or supplier; agreement with Secretary; publication of directories; availability; inclusion of program in explanation of benefits; payment of claims on assignment-related basis

(1) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term "participating physician or supplier" means a physician or supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) Each carrier having an agreement with the Secretary under subsection (a) of this section shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty,

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and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). Each such carrier shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which a carrier having an agreement with the Secretary under subsection (a) of this section is able to develop a system for the electronic transmission to such carrier of bills for services, such carrier shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1395ss(g)(1) of this title) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by a carrier with a contract under this section, the carrier shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by a carrier, whether electronically or otherwise, and such user fees shall be collected and retained by the carrier.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of carriers, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include--

(i) a description of the participation program,

(ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,

(iii) an explanation of the assistance offered by carriers in obtaining the names of participating physicians and suppliers, and

(iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1395l(a)(1) of this title (made other than on an assignment-related basis), shall include--

(A) a prominent reminder of the participating physician and supplier program established under this subsection

(including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,

(C) (i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and **(ii)** an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1395w-4(g) of this title, information regarding such applicable limiting charge (including information concerning the right to a refund under section 1395w-4(g)(1)(A)(iv) of this title).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(i) Definitions

For purposes of this subchapter:

(1) A claim is considered to be paid on an "assignment-related basis" if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii) of this section, in accordance with subsection (b)(6)(B) of this section, or under the procedure described in section 1395gg(f)(1) of this title.

(2) The term "participating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (h)(1) of this section); the term "nonparticipating physician" refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term "nonparticipating supplier or other person" means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1) of this section).

(3) The term "percentage increase in the MEI" means, with respect to physicians' services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3) of this section) applicable to such services furnished as of the first day of that year.

(4) The term "primary care services" means physicians' services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j) Monitoring of charges of nonparticipating physicians; sanctions; restitution

(1)(A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician's actual charges to individuals enrolled under this part for physicians' services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician's actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of each such physician for physicians' services furnished to individuals enrolled under this part. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined

under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians' service furnished by a nonparticipating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician's maximum allowable actual charge for that service in the previous year was--

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv) of this section) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv) of this section) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician's maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians' service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is--

(I) for 1987, 1/4,

(II) for 1988, 1/3,

(III) for 1989, 1/2 , and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) of this section in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) 1/2 of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to--

(I) an adjustment under subsection (b)(8)(B) of this section (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) of this section (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) of this section (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A) of this section,

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii) of this section, and

(VI) an adjustment under section 1395l(l)(3)(B) of this title (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action--

(I) under subsection (b)(8)(B) of this section, the inherently reasonable charge established under subsection (b)(8) of this section;

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) of this section or under section 1395l(l)(3)(B) of this title, the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii) of this section, the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are--

(A) excluding a physician from participation in the programs under this chapter for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1320a-7 of this title, or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1320a-7a(a) of this title,

or both. The provisions of section 1320a-7a of this title (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1320a-7a(a) of this title, except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k) Sanctions for billing for services of assistant at cataract operations

(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section in the case of surgery performed on or after March 1, 1987.

(l) Prohibition of unassigned billing of services determined to be medically unnecessary by carrier

(1)(A) Subject to subparagraph (C), if--

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,

(ii) payment for such services is not accepted on an assignment-related basis,

(iii) (I) a carrier determines under this part or a peer review organization determines under part B of subchapter XI of this chapter that payment may not be made by reason of section 1395y(a)(1) of this title because a service otherwise covered under this subchapter is not reasonable and necessary under the standards described in that section or (II) payment under this subchapter for such services is denied under section 1320c-3(a)(2) of this title by reason of a determination under section 1320c-3(a)(1)(B) of this title, and

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if--

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the

physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(iii)(I) if--

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1395y(a)(1) of this title, or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service.

(2) Each carrier with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of subchapter XI of this chapter shall send any notice of denial of payment for physicians' services based on section 1395y(a)(1) of this title and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(m) Disclosure of information of unassigned claims for certain physicians' services

(1) In the case of a nonparticipating physician who--

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician's actual charge is at least $500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

(n) Elimination of markup for certain purchased services

(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1395x(s)(3) of this title (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part--

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(o) Reimbursement for drugs and biologicals

(1) If a physician's supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) A drug or biological furnished before January 1, 2004.

(ii) Blood clotting factors furnished during 2004.

(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

(iv) A vaccine described in subparagraph (A) or (B) of section 1395x(s)(10) of this title furnished on or after January 1, 2004.

(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(B) In the case of a drug or biological furnished during 2004 that is not described in--

(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

(ii) subparagraph (D)(i), or

(iii) subparagraph (F), the amount determined under paragraph (4).

(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1395w-3 of this title, section 1395w-3a of this title, section 1395w-3b of this title, or section 1395rr(b)(13) of this title, as the case may be for the drug or biological.

(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1395x(n) of this title on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1395w-3 of this title on or after January 1, 2007, the amount provided under section 1395w-3 of this title.

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished--

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1395w-3a of this title.

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1395x(n) of this title that are furnished--

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

(ii) in 2005 and subsequent years, the amount provided under section 1395w-3a of this title for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).

(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled "Average of GAO and OIG data (percent)" in the table entitled "Table 3.--Medicare Part B Drugs in the Most Recent GAO and OIG Studies" published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled "Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost", provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1395x(s)(2) of this title and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p) Requiring submission of diagnostic information

(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) of this section for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) of this section on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)--

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a carrier, the physician may be subject to a civil money penalty in an amount not to exceed $2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in subsection (j)(2)(A) of this section.

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1395x(s) of this title ordered by a physician or a practitioner specified in subsection (b)(18)(C) of this section, but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

(q) Anesthesia services; counting actual time units

(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall

establish by regulation a relative value guide for use in all carrier localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this subchapter for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

(B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of--

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238- 36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in subsec. (b)(14)(C)(iv) of this section for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

(r) Establishment of physician identification system

The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this subchapter. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s) Application of fee schedule

(1) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis. Any fee schedule established under this paragraph for such item or service shall be updated each year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year, except that in no event shall a fee schedule for an item described in paragraph (2)(D) be updated before 2003.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1395rr(b)(8) of this title).

(C) Therapeutic shoes.

(D) Parenteral and enteral nutrients, equipment, and supplies.

(E) Electromyogram devices.

(F) Salivation devices.

(G) Blood products.

(H) Transfusion medicine.

(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1395w-3(a) of this title--

(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1395w-3 of this title, and in the case of such adjustment, paragraphs (8) and (9) of section 1395u(b) of this title shall not be applied.

(t) Requests for payment or bill submitted to include medicare provider number

Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility for which payment may be made under this part shall include the facility's medicare provider number.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XVIII, § 1842, as added July 30, 1965, Pub.L. 89-97, Title I, § 102(a), 79 Stat. 309, and amended Jan. 2, 1968, Pub.L. 90- 248, Title I, § § 125(a), 154(d), 81 Stat. 845, 863; Oct. 30, 1972, Pub.L. 92-603, Title II, § § 211(c)(3), 224(a), 227(e)(3), 236(a), 258(a), 262(a), 263(d)(5), 281(d), 86 Stat. 1384, 1395, 1407, 1414, 1447 to 1449, 1455; Oct. 16, 1974, Pub.L. 93-445, Title III, § 307, 88 Stat. 1358; Dec. 31, 1975, Pub.L. 94-182, Title I, § 101(a), 89 Stat. 1051; July 16, 1976, Pub.L. 94-368, § § 2, 3(a), (b), 90 Stat. 997; Oct. 25, 1977, Pub.L. 95-142, § 2(a)(1), 91 Stat. 1175; Dec. 20, 1977, Pub.L. 95-216, Title V, § 501(b), 91 Stat. 1565; Dec. 5, 1980, Pub.L. 96-499, Title IX, § § 918(a)(1), 946(a), (b), 948(b), 94 Stat. 2625, 2642, 2643; Aug. 13, 1981, Pub.L. 97-35, Title XXI, § 2142(b), 95 Stat. 798; Sept. 3, 1982, Pub.L. 97-248, Title I, § § 104(a), 113(a), 128(d)(1), 96 Stat. 336, 340, 367; July 18, 1984, Pub.L. 98-369, Div. B, Title III, § § 2303(e), 2306(a), (b)(1), (c), 2307(a)(1), (2), 2326(c)(2), (d)(2), 2339, 2354(b)(13), (14), Title VI, § 2663(j)(2)(F)(iv), 98 Stat. 1066, 1070, 1071, 1073, 1087, 1088, 1093, 1101, 1170; Nov. 8, 1984, Pub.L. 98-617, § 3(a)(1), (b)(5), (6), 98 Stat. 3295, 3296; Apr. 7, 1986, Pub.L. 99-272, Title IX, § § 9219(b)(1)(A), (2)(A), 9301(b)(1), (2), (c)(2) to (4), (d)(1) to (3), 9304(a), 9306(a), 9307(c), 100 Stat. 182 to 188, 190, 193, 194; Oct. 21, 1986, Pub.L. 99-509, Title IX, § § 9307(c)(2)(A), 9311(c), 9320(e)(3), 9331(a)(1) to (3), (b)(1) to (3), (c)(3)(A), 9332(a)(1), (b)(1), (2), (c)(1), (d)(1), 9333(a), (b), 9334(a), 9338(b), (c), 9341(a)(2), 100 Stat. 1995, 1998, 2015, 2018 to 2026, 2028, 2035, 2038; Oct. 22, 1986, Pub.L. 99-514, Title XVIII, § 1895(b)(14)(A), (15), (16)(A), 100 Stat. 2934; Aug. 18, 1987, Pub.L. 100-93, § 8(c)(2), 101 Stat. 692; Dec. 22, 1987, Pub.L. 100-203, Title IV, § § 4031(a)(2), 4035(a)(2), 4041(a)(1)(B), (3)(A), 4042(a) to (c), 4044(a), 4045(a), (c)(1), (2)(B), (D), 4046(a), 4047(a), 4048(a), (e), 4051(a), 4052(a), 4053(a), formerly 4052(a), 4054(a), formerly 4053(a), 4063(a), 4081(a), 4082(c), 4085(g)(1), (i)(5) to (7), (i)(22)(C), (24) to (27), 4096(a)(1), 101 Stat. 1330-76, 1330-78, 1330-83, 1330-85 to 1330-87, 1330-89, 1330-93, 1330-97, 1330-109, 1330-126, 1330-128, 1330-131, 1330-132, 1330-139; renumbered and amended July 1, 1988, Pub.L. 100-360, Title II, § § 201(c), 202(c)(1), (e)(1) to (3)(A), (C), (4)(A), (5), (g), 223(b),

(c), Title IV, § 411(a)(3)(A), (C)(i), (f)(1)(A), (B), (2)(C) to (F), (3)(A), (B), (4)(A) to (C), (5), (6)(B), (7)(A), (B), (9), (11)(A), (14), (g)(2)(A) to (C), (i)(1)(A), (2), (4)(C)(vi), (j)(4)(A), 102 Stat. 702, 713, 716, 717, 747, 768, 776 to 781, 783, 787, 788, 789, 790, 791; Oct. 13, 1988, Pub.L. 100-485, Title VI, § 608(d)(5)(A) to (D), (F) to (H), (17), (21)(A), (B), (D), (24)(B), 102 Stat. 2414, 2418, 2420, 2421; Dec. 13, 1989, Pub.L. 101-234, Title II, § 201(a)(1), Title III, § 301(b)(2), (6), (c)(2), (d)(3), 103 Stat. 1981, 1985, 1986; Dec. 19, 1989, Pub.L. 101-239, Title VI, § § 6003(g)(3)(D)(ix), 6102(b), (e)(2) to (4), (9), 6104, 6106(a), 6107(b), 6108(a)(1), (b)(1), (2), 6114(b), (c), 6202(d)(2), 103 Stat. 2153, 2184, 2187, 2188, 2208 to 2210, 2212, 2213, 2218, 2234; Nov. 5, 1990, Pub.L. 101-508, Title IV, § § 4101(a), (b)(1), 4103, 4105(a)(1), (2), (b)(1), 4106(a)(1), (b)(2), 4108(a), 4110(a), 4118(a)(1), (2), (f)(2)(A) to (C), (i)(1), (j)(2), 4155(c), 104 Stat. 1388-54, 1388-58 to 1388-63, 1388-66, 1388-67, 1388-69 to 1388-71, 1388-87; Nov. 16, 1990, Pub.L. 101-597, Title IV, § 401(c)(2), 104 Stat. 3035; Aug. 10, 1993, Pub.L. 103-66, Title XIII, § § 13515(a)(2), 13516(a)(2), 13517(b), 13568(a), (b), 107 Stat. 583 to 585, 608; Oct. 31, 1994, Pub.L. 103-432, Title I, § § 123(b)(1), (2)(B), (c), 125(a), (b)(1), 126(a)(1), (c), (e), (g)(9), (h)(2), 135(b)(2), 151(b)(1)(B), (2)(B), 108 Stat. 4411 to 4416, 4423, 4434; Aug. 21, 1996, Pub.L. 104-191, Title II, § § 202(b)(2), 221(b), 110 Stat. 1998, 2011; Aug. 5, 1997, Pub.L. 105-33, Title IV, § § 4201(c)(1), 4205(d)(3)(B), 4302(b), 4315(a), 4316(a), 4317, 4432(b)(2), (4), 4512(b)(2), (c), 4531(a)(2), 4556(a), 4603(c)(2)(B)(i), 4611(d), 111 Stat. 251, 382, 390, 392, 421, 444, 450, 462, 473; Nov. 29, 1999, Pub.L. 106-113, Div. B, § 1000(a)(6) [Title II, § 223(c), Title III, § § 305(a), 321(k)(4)], 113 Stat. 1536, 1501A-353, 1501A-361, 1501A-366; Dec. 21, 2000, Pub.L. 106-554, Title I, § 1(a)(6) [Title I, § § 105(d), 114(a), Title II, § 222(a), Title III, § 313(b)(1), (2), Title IV, § 432(b)(2)], 114 Stat. 2763, 2763A-472, 2763A-473, 2763A-487, 2763A-499, 2763A-526; Dec. 8, 2003, Pub.L. 108-173, Title III, § § 302(d)(3), 303(b), (e), (g)(1), (i)(1), 305(a), Title VII, § 736(b)(8), (9), Title IX, § 952(a), (b), 117 Stat. 2233, 2238, 2252 to 2255, 2356, 2427.)

AMENDMENT OF HEADING

<Pub.L. 108-173, Title IX, § 911(c)(1), (d), Dec. 8, 2003, 117 Stat. 2383, 2385, provided that, effective Oct. 1, 2005, the heading is amended to read as follows: "Provisions relating to the administration of part B of this subchapter".>

AMENDMENT OF SUBSEC. (A)

<Pub.L. 108-173, Title IX, § 911(c)(2), (d), Dec. 8, 2003, 117 Stat. 2383, 2385, provided that, effective Oct. 1, 2005, subsection (a) is amended to read as follows:>

<**(a)** The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk-1 of this title.>

REPEAL OF SUBSEC. (B)(1)

<Pub.L. 108-173, Title IX, § 911(c)(3)(A), (d), Dec. 8, 2003, 117 Stat. 2383, 2385, provided that, effective Oct. 1, 2005, subsection (b) is amended by striking paragraph (1).>

REPEAL OF SUBSEC. (B)(2)(A), (B)

<Pub.L. 108-173, Title IX, § 911(c)(3)(B)(i), (d), Dec. 8, 2003, 117 Stat. 2383, 2385, provided that, effective Oct. 1, 2005, subsection (b)(2) is amended by striking subparagraphs (A) and (B).>

AMENDMENT OF SUBSEC. (B)(2)(C)

<Pub.L. 108-173, Title IX, § 911(c)(3)(B)(ii), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(2) is amended in subparagraph (C), by striking "carriers" and inserting " medicare administrative contractors".>

REPEAL OF SUBSEC. (B)(2)(D), (E)

<Pub.L. 108-173, Title IX, § 911(c)(3)(B)(iii), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that,

effective Oct. 1, 2005, subsection (b)(2) is amended by striking subparagraphs (D) and (E).>

AMENDMENT OF SUBSEC. (B)(3)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(i), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended in the matter before subparagraph (A), by striking "Each such contract shall provide that the carrier" and inserting "The Secretary".>

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(viii), (ix), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended in the first sentence, after subparagraph (L), by striking "and shall contain" and all that follows through the period; and in the seventh sentence, by inserting "medicare administrative contractor," after "carrier,".>

AMENDMENT OF SUBSEC. (B)(3)(A), (B), (F) TO (H), (L)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(ii), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended by striking "will" the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting "shall".>

AMENDMENT OF SUBSEC. (B)(3)(B)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(iii), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended in subparagraph (B), in the matter before clause (i), by striking "to the policyholders and subscribers of the carrier" and inserting "to the policyholders and subscribers of the medicare administrative contractor".>

REPEAL OF SUBSEC. (B)(3)(C) TO (E)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(iv), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended by striking subparagraphs (C), (D), and (E).>

AMENDMENT OF SUBSEC. (B)(3)(H)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(v), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3)(H) is amended by striking "if it makes determinations or payments with respect to physicians' services," in the matter preceding clause (i); and by striking "carrier" and inserting "medicare administrative contractor" in clause (i).>

REPEAL OF SUBSEC. (B)(3)(I)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(vi), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended by striking subparagraph (I).>

AMENDMENT OF SUBSEC. (B)(3)(L)

<Pub.L. 108-173, Title IX, § 911(c)(3)(C)(vii), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b)(3) is amended in subparagraph (L), by striking the semicolon and inserting a period.>

REPEAL OF SUBSEC. (B)(5)

<Pub.L. 108-173, Title IX, § 911(c)(3)(D), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b) is amended by striking paragraph (5).>

42 U.S.C.A. § 1395u

AMENDMENT OF SUBSEC. (B)(6)(D)(IV)

<Pub.L. 108-173, Title IX, § 911(c)(3)(E), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b) is amended in paragraph (6)(D)(iv), by striking "carrier" and inserting "medicare administrative contractor".>

AMENDMENT OF SUBSEC. (B)(7)

<Pub.L. 108-173, Title IX, § 911(c)(3)(F), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (b) is amended in paragraph (7), by striking "the carrier" and inserting "the Secretary" each place it appears.>

REPEAL OF SUBSEC. (C)(1)

<Pub.L. 108-173, Title IX, § 911(c)(4)(A), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (c) is amended by striking paragraph (1).>

AMENDMENT OF SUBSEC. (C)(2)(A)

<Pub.L. 108-173, Title IX, § 911(c)(4)(B), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (c) is amended in paragraph (2)(A), by striking "contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B)," and inserting "contract under section 1395kk-1 of this title that provides for making payments under this part".>

AMENDMENT OF SUBSEC. (C)(3)(A)

<Pub.L. 108-173, Title IX, § 911(c)(4)(C), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (c) is amended in paragraph (3)(A), by striking "subsection (a)(1)(B)" and inserting "section 1395kk-1(a)(3)(B) of this title".>

AMENDMENT OF SUBSEC. (C)(4)

<Pub.L. 108-173, Title IX, § 911(c)(4)(D), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (c) is amended in paragraph (4), in the matter preceding subparagraph (A), by striking "carrier" and inserting "medicare administrative contractor".>

REPEAL OF SUBSEC. (C)(5), (6)

<Pub.L. 108-173, Title IX, § 911(c)(4)(E), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (c) is amended by striking paragraphs (5) and (6).>

REPEAL OF SUBSEC. (D) TO (F)

<Pub.L. 108-173, Title IX, § 911(c)(5), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsections (d), (e), and (f) are repealed.>

AMENDMENT OF SUBSEC. (G)

<Pub.L. 108-173, Title IX, § 911(c)(6), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (g) is amended by striking "carrier or carriers" and inserting "medicare administrative contractor or contractors".>

AMENDMENT OF SUBSEC. (H)(2)

<Pub.L. 108-173, Title IX, § 911(c)(7)(A), (d), Dec. 8, 2003, 117 Stat. 2384, 2385, provided that, effective Oct. 1, 2005, subsection (h)(2) is amended by striking "Each carrier having an agreement with the Secretary under subsection (a) of this section" and inserting "The Secretary"; and by striking "Each such carrier" and inserting "The Secretary".>

AMENDMENT OF SUBSEC. (H)(3)(A)

<Pub.L. 108-173, Title IX, § 911(c)(7)(B), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (h) is amended in paragraph (3)(A), by striking "a carrier having an agreement with the Secretary under subsection (a)" and inserting "medicare administrative contractor having a contract under section 1395kk-1 of this title that provides for making payments under this part"; and by striking "such carrier" and inserting "such contractor".>

AMENDMENT OF SUBSEC. (H)(3)(B)

<Pub.L. 108-173, Title IX, § 911(c)(7)(C), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (h) is amended in paragraph (3)(B) by striking "a carrier" and inserting "a medicare administrative contractor" each place it appears; and by striking "the carrier" and inserting "the contractor" each place it appears.>

AMENDMENT OF SUBSEC. (H)(5)(A), (B)(III)

<Pub.L. 108-173, Title IX, § 911(c)(7)(D), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (h) is amended in paragraphs (5)(A) and (5)(B)(iii), by striking "carriers" and inserting "medicare administrative contractors" each place it appears.>

AMENDMENT OF SUBSEC. (L)(1)(A)(III)

<Pub.L. 108-173, Title IX, § 911(c)(8)(A), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (l) is amended in paragraph (1)(A)(iii), by striking "carrier" and inserting "medicare administrative contractor".>

AMENDMENT OF SUBSEC. (L)(2)

<Pub.L. 108-173, Title IX, § 911(c)(8)(B), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (l) is amended in paragraph (2), by striking "carrier" and inserting "medicare administrative contractor".>

AMENDMENT OF SUBSEC. (P)(3)(A)

<Pub.L. 108-173, Title IX, § 911(c)(9), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (p)(3)(A) is amended by striking "carrier" and inserting "medicare administrative contractor".>

AMENDMENT OF SUBSEC. (Q)(1)(A)

<Pub.L. 108-173, Title IX, § 911(c)(10), (d), Dec. 8, 2003, 117 Stat. 2385, provided that, effective Oct. 1, 2005, subsection (q)(1)(A) is amended by striking "carrier".>

AMENDMENT OF SUBSEC. (S)(2)

<Pub.L. 108-173, Title VI, § 627(b)(2), (c), Dec. 8, 2003, 117 Stat. 2321, provided that, applicable to items furnished on or after Jan. 1, 2005, (s)(2) is amended by striking subparagraph (C).>

42 U.S.C.A. § 1395u

Pub.L. 108-173, Title IX, § 952(c), Dec. 8, 2003, 117 Stat. 2427, provided that: "The amendments made by this section [amending subsec. (b)(6) of this section] shall apply to payments made on or after the date of the enactment of this Act [Dec. 8, 2003]."

42 U.S.C.A. § 1395u, 42 USCA § 1395u

END OF DOCUMENT

EXHIBIT BF

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

- - - - - - - - - - - - - - - -x

IN RE: PHARMACEUTICAL	:	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	:	CIVIL ACTION
PRICE LITIGATION	:	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:	
U.S. ex rel. Ven-a-Care of	:	Judge Patti B. Saris
the Florida Keys, Inc.	:	
v.	:	
Abbott Laboratories, Inc.,	:	Chief Magistrate
No. 06-CV-11337-PBS	:	Judge Marianne B.
- - - - - - - - - - - - - - - -x		Bowler

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subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of --
A. As of October 2003.
Q. That's correct, isn't it?
A. I guess it is. That's what the statute says. Another piece of sausage. I have just forgotten that we did that, to be honest with you, which I assume is why they don't have a dispensing fee for anything but respiratory drugs, because they didn't do that for respiratory drugs.
Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion, has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?
MR. GOBENA: Object to the form. The legislation speaks for itself.
MR. BREEN: Objection to the form.
BY MR. DALY:
Q. You can go ahead.
A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed

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by members. I'm sure the staff -- staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.
Q. And are you aware of whether the drugs that DOJ is suing Abbott for, many of those drugs are used in the home infusion context and using DME?
MR. GOBENA: Objection to form.
THE WITNESS: As of today, I'm aware of it. I wasn't aware of it before.
BY MR. DALY:
Q. But as of today, you are?
A. Yes. Obviously looking at the drug list.
Q. Page 27 of Exhibit Abbott 191, which is your 10-3 -- yes, your October 3 -- excuse me, October 3, 2002 testimony. I just want to direct you

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to page 27.
A. 27?
Q. Yes.
A. Okay.
Q. And in your testimony in response to Mr. English, you indicate that you think -- well, you state, "I think there are a lot of different provider areas that may have small impacts from AWP, and we are certainly willing to work with the committee to identify those." And then you mentioned oncology as -- oncology and dialysis and hematology being sort of the big three, right?
A. Yes.
Q. And then you say, "I think almost every physician to some degree that administers drugs probably has some beneficial cost shifting benefit from AWP, I think those are the three big areas," you see that language?
A. Yes.
Q. And that was a true statement, correct?
A. Yes.
Q. On page 31, I just want to get a fix for

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-- and we may have covered this in some part in the sort of background section that we did at the beginning, but you state at the bottom of the page, "I had been working on Medicare for over 20 years and there has never been any law passed more complicated than this one." How far back does your work on Medicare go?
A. In a minor way, probably 1982. But in a full time way, 1989.
Q. And what were you doing with respect to Medicare in 1982?
A. Not much. Occasional staff work for Senator Gorton, but very, you know, minor.
Q. And '89 would have started your work with the Bush Administration?
A. And OMB. Yes.
Q. And if you would turn to page 34. If you -- actually, if you look at 33, the page before, it looks like you finished up your testimony, and then George Reeb, R-E-E-B, got in the hot seat. And began to talk a little bit about Medicare and Medicaid. And on page 34 of Mr. Reeb's testimony, he states

suggested that they need these Medicare drug profits to cross-subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs such as the administration of chemotherapy for cancer." Do you see that language?
A. Yes.
Q. And you were aware during this time period that that was the contention of many providers, correct?
MR. GOBENA: Object to the form.
THE WITNESS: I was aware that that was primarily the contention of oncologists.
BY MR. DALY:
Q. And the convention was that the oncologists were using the overpayment on the Medicare Part B drugs to cross-subsidize inadequate service payments under Medicare, is that your understanding?
MR. GOBENA: Object to the form.
THE WITNESS: That was their contention. Yes.
BY MR. DALY:

Q. And you understood that to be their contention?
A. I certainly understood that to be their contention. Yes.
Q. If you skip ahead to page 4. Do you see under Medicare payment for currently covered drugs in the second sentence, you say, "traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia, such as the Red Book, which is published by Medical Economics Company, Inc."
Do you see that language?
A. Yes.
Q. I just want to ask you a couple of questions about that. Is it your understanding that manufacturers actually report AWP?
MR. GOBENA: Object to the form.
THE WITNESS: It was my understanding at this time that manufacturers basically self-reported to the Red Book, which is then used as AWP as the standard measurement, as a reference matter for most of the carriers.

BY MR. DALY:
Q. Is your understanding different than that today?
A. At the time, I think I believed that that was basically the -- under the rules, that was what CMS had used and then we had very little ability to change that without a full rule making.
I'm not sure in hindsight if that was correct, but my understanding at the time was, with staff, that we would have to undergo full rule making to change that. And that essentially the Red Book was the de facto price that was used by the carriers and CMS to pay 95 percent AWP.
Q. What I'm trying to get to is whether or not it's your understanding that as a general proposition, manufacturers submit AWP to the compendia, or they submit some other price to the compendia, which the compendia then marks up to achieve the AWP?
MR. GOBENA: Object to the form.
THE WITNESS: My understanding was that the manufacturers subject a price to the Red Book,

which is then published as the compendia. That they submit it. That was my understanding. It may not be correct.
BY MR. DALY:
Q. All right. So at this point in time, and perhaps now, you do not have an understanding that manufacturers submit a list price or direct price or WAC or some other price, and that the compendia then marked that price up by a percentage and lists that as the AWP?
MR. GOBENA: Object to the form.
MS. MILLER: Object to the form.
THE WITNESS: I was not -- my understanding was that they submitted the AWP to the Red Book.
BY MR. DALY:
Q. And was it your understanding that the, that the AWP that CMS was using as the benchmark for reimbursement was the AWP that was published in the compendia?
A. For the most part, it was my understanding that the standard practice was that 95 percent of AWP

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was the AWP that was published in the Red Book.
Q. And that's what you understood the law and regulations to require?
A. That's what I understood at the time. At the time, that's what I believe the law and regulations required. It's my recollection. I probably knew it better at the time than I do now.
Q. In the next paragraph, you state, "this committee," which is the Energy and Commerce Committee, "CMS and the OIG have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs." Do you see that language?
A. Yes.
Q. And you had been aware of the shortcomings of AWP as a way for Medicare to reimburse drugs since your work on this in '90-'91 as we discussed this morning, correct?
MR. GOBENA: Object to the form.
MR. BREEN: Object to the form.
BY MR. DALY:
Q. Go ahead.
A. Yes. Generally, I was aware.

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Q. And in the next sentence, you say, "the IG," that's the Inspector General, "has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities and DME suppliers are actually significantly less than the AWP reported in the Red Book and like publications." Do you see that language?
MR. GOBENA: Object to the form.
THE WITNESS: Yes.
BY MR. DALY:
Q. And the numerous reports referred to here are the various OIG reports that you had been familiar with during this time period, correct?
MR. GOBENA: Object to the form.
MR. BREEN: Object to the form.
THE WITNESS: Yes. I think GAO is one.
BY MR. DALY:
Q. GAO reports as well?
A. GAO as well.
Q. If you go over to -- we are on page 5 now, in the carryover paragraph at the top. You have a

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sentence that says, "by offering physicians and providers deep discounts compared to the price they could bill Medicare, the drug manufacturers are able to use profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries." Do you see that language?
A. Yes.
Q. And is that something you believed at the time?
A. Something I still believe.
Q. You're aware of how generic drugs are reimbursed under Medicare, correct?
A. Yes.
Q. In the sense that if there are multiple source drugs, they are typically reimbursed under a J Code, correct?
A. Yes.
Q. And the J Code is typically the median AWP between all of the participants in the J Code, correct?
MR. GOBENA: Object to the form.
THE WITNESS: Yes.

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BY MR. DALY:
Q. Is that your understand --
A. Generally.
Q. Okay. And so if you have, I mean, five participants in a J Code, five different brands of a particular drug that are captured within a single J Code, if a provider were to use that J Code, the provider would put in whatever the J Code median is for that J Code, correct, as his reimbursement?
MR. GOBENA: Object to the form.
MR. BREEN: Objection to the form. Breen, objection, form.
MR. GOBENA: And Gobena, objection, form.
THE WITNESS: I'm generally familiar with it.
BY MR. DALY:
Q. And is what I said generally correct?
MR. GOBENA: Object to the form.
THE WITNESS: I believe so. Yes.
BY MR. DALY:
Q. So that I just want to understand in terms of what you wrote here, if you're within a J Code,

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generally, that with generic products, as a general proposition, WAC prices over time declined to reflect competition?
MR. NEAL: Object to the form. You can answer.
A. I didn't know that.
Q. Did you know that to the extent some drugs end up having high spreads it's because -- some generic drugs -- end up with high spreads it's because prices keep getting lower and lower as there's more competition?
MR. NEAL: Objection.
MR. RIKLIN: Objection to form.
A. I was aware of that.
Q. So were you aware that -- that increasing spreads were --
A. But prices get lower and lower to the providers, not to the government.
Q. Well, to the providers, in the sense that the, for example, the WAC keeps declining?
A. Right.
Q. And AMPs would keep declining, as well;

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right?
MR. NEAL: Objection to form. You can answer.
BY MR. ESCOBAR:
Q. Well, that would be -- that would generally be true; right?
MR. RIKLIN: Objection to form.
BY MR. ESCOBAR:
Q. And so the government would be able to see that the life of a drug like Albuterol that the WACs and the AMPs decline over time; right?
MR. RIKLIN: Objection to form.
MR. NEAL: I'll join in the objection. You can answer.
A. Yes.
Q. Now, if you turn to page 13 of the complaint, Exhibit Dey 028, just read to yourself paragraph 40?
A. Yes.
Q. Okay. Now, this was a complaint that was signed the 22nd day of August, 2006, and on paragraph 40, in the first sentence, it says, AWP

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is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient; do you see that?
A. Yes.
Q. That's not what AWP was viewed as, that's not the view of CMS as to what AWP was, is it?
MR. NEAL: Objection as to form.
BY MR. ESCOBAR:
Q. Is it?
MR. NEAL: This is not a 30 (b)(6), this is not a 30 (b)(6) deposition. You can answer.
A. No, I don't think that's what AWP is commonly considered to be, I think that's an inaccurate description.
Q. In fact, that's a completely inaccurate statement of AWP; right?
MR. NEAL: Objection as to form.
A. I think it's probably a poor description, yes.

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Q. Because it's not accurate?
A. Yes.
MR. NEAL: Objection as to form.
BY MR. ESCOBAR:
Q. Now, you would think that -- well, let's take the next one -- WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who will then resell it to a retail customer; do you see that?
A. Yes.
Q. And that's a description of what WAC is, is also not accurate; is it?
MR. NEAL: Objection as to form.
A. Well, a little closer.
Q. But it's not accurate, is it?
MR. NEAL: Objection.
A. Probably not totally accurate.
Q. In fact, that sentence, where the government describes in the complaint against Dey what WAC is, this does not include the fact that it's -- it lists price before discounts, which is

document speaks for itself.
A. I don't know. I would have to read the whole -- yeah, I'm not sure of the context it's in. I'd --
Q. Well, let's talk about paragraph 42. The sentence reads that AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient, to start with, do you use average wholesale price to refer to the price at which a firm sells a drug to a wholesaler or a customer?
MR. GOBENA: Object to the form.
A. Do I -- do I have my government context, I would say no.
Q. All right. Have you ever used average wholesale price to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?
A. No.
MR. GOBENA: Object to the form.
BY MR. COOK:

Q. Have you ever heard anybody else use AWP to refer to the price of which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?
MR. GOBENA: Object to the form.
A. No.
Q. And when you talk about what average wholesale price is supposed to be you're referring to, I assume, and you can tell me if I'm correct, the dictionary definition for the words, average, wholesale, and price?
A. Yes.
Q. You're not referring to the manner in which it's ever been used, commonly, in the industry; correct?
MR. GOBENA: Object to the form.
MR. KELLEY: Objection to form.
A. Yes, the definition is the same as average sales price or average manufacturers price, you would think that -- there are a million ways to implement them and to actually define them. I mean, they're basic concepts.

Q. All right. But paragraph 42, in front of you, certainly does not describe any way in which the government has ever defined AWP; correct?
MR. GOBENA: Object to the form. This is not a 30(b)(6) witness on behalf of the government.
MR. RIKLIN: Objection.
A. My experience is that -- that in my terms with the government nobody looked at what the price of what AWP would pay.
MR. COOK: I have no more questions. Thank you.
MR. GOBENA: All right. We'll let go of this witness.
THE VIDEOGRAPHER: The time is 5:00 -- the time is 5:05 -- the time is 5:05 P.M. We're going off the record, concluding tape number six, and this days' testimony, and volume two of the deposition of Thomas Scully in the matter of in re Pharmaceutical Industry Average Wholesale Price Litigation. This deposition contains five

tapes, or six tapes.
(Signature having not been waived, the deposition of Thomas Scully was concluded at 5:06 P.M.)

ACKNOWLEDGMENT OF DEPONENT

I, Thomas Scully, do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

_____ _____
(DATE) (SIGNATURE)

EXHIBIT BG

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.	:	CIVIL ACTION: 06-CV-11337-PBS

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA, Plaintiff, v. ABBOTT LABORATORIES, INC., et al., Defendants.	:	CASE NO. CV-05-219 JUDGE CHARLES PRICE

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make it through the House legislative process. Whether at the committee level or at the full House level I don't recall.
Q. And that would be for the proposed 1998 budget?
A. That would be in the Balanced Budget Act which addressed the Fiscal 1998 budget.
Q. And that would be the legislation that legislated that Medicare Part B reimbursement would be at 95 percent of AWP. Correct?
A. I don't recall what our original proposal was, and I don't recall the details of the legislative process. I think it came out the other end at 95 percent.
Q. Right. The ultimate legislation.
A. The ultimate legislation called for 95 percent of AWP, yes.
Q. And the AWP in that legislation, did you understand that in the same way you understood AWP in the regulation from 1992?
A. Yes.
MS. BROOKER: Objection. Form.

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Q. And so that would refer to a published average wholesale price. Correct?
A. That was our understanding of it, yes.
Q. And the next cc is Teruni, T-E-R-U-N-I, Rosengren, R-O-S-E-N-G-R-E-N, with the GAO. Do you know who Mr. or Ms. Rosengren is?
A. No, I do not.
Q. There is Michael Hertz, United States Department of Justice. Do you know who Mr. Hertz is?
A. Mr. Hertz was a senior person in the civil litigation side of the Department of Justice, from my understanding. I, in fact, had met Mr. Hertz and worked with him on an other number of occasions.
Q. And the next are Mr. Breen and Mr. Wampler from the Wampler, Buchanan and Breen firm, Mr. Breen here in the flesh, and Mr. Wampler. Do you -- and at the time did you know who Mr. Wampler and Mr. Breen were?
A. No. I had not had the pleasure.
Q. Okay. I'd like to show you one last

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exhibit, and then we'll let you go promptly at 4 to your call.
MR. COOK: We will mark this, as soon as we go off the record, as Exhibit Abbott 165.
For the record, it's a printout of a Wall Street Journal article dated May 12th, 2000, entitled "Medicare monitor, how a whistleblower-spurred pricing case involved drug makers." And the second sub bullet, "Toilet seat as a talking point."
Q. I'll ask you to take a quick look that and ask you, do you recall that?
A. I recall the newspaper story. I recall being interviewed for it.
Q. And tell me what you recall about the interview for that newspaper story.
A. Ms. McGinley, the reporter from the Wall Street Journal, with whom I had worked with quite a bit over the time, called me and told me that she was asking about it. She asked me if I remembered the toilet seat, and I think she probably pretty accurately reported in this

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newspaper story my response to her.
Q. And that response on this Page 2 of this particular printout is on the fourth paragraph up from the bottom. And I'll read it for the record, attributed to you:
"I thought the toilet seat was clever, but the tone of the letter was so hostile that it took all the fun out of it. We were not unaware of the problem, we were just moving slowly."
Do I understand correctly that you were accurately quoted as saying that HCFA was not unaware of the problem when you received the letter in June of 1997?
MS. BROOKER: Objection. Form.
A. We were not unaware of certainly the Medicare problem, which was the one we were -- I was focused on.
Q. And the one described in the letter. Correct?
A. That is correct.
MR. COOK: It's 4:02. I have blown two minutes past your prompt 4:00 adjournment time.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.	:	CIVIL ACTION: 06-CV-11337-PBS

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA, Plaintiff, v. ABBOTT LABORATORIES, INC., et al., Defendants.	:	CASE NO. CV-05-219 JUDGE CHARLES PRICE

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Q. And for a brand name drug, would you -- at the time, did you expect that there would be much variation between various purchasers based upon volume purchases of the brand name drug?
A. I believe we had a perception that the bigger the purchaser, the larger the discount they were likely to be able to achieve; that the very largest pharmacy chains, for instance, or hospital group purchasing operations, probably received the most favorable prices, but that that would be -- and that some small independent pharmacies might actually pay average wholesale price as described in the compendia; that there would be a range below that in which most of the prices would actually occur.
Q. Turning to generic drugs for a minute, what do you understand to be the differences between the market for brand name drugs and the market for generic drugs?
MS. BROOKER: Objection. Form.
A. If we're going back to 1997 --
Q. Correct.

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A. -- I think it's fair to say that I had really only a very limited understanding of the marketplace for generic drugs and an even more limited understanding of the difference between the market for generic drugs and for brand drugs.
And, again, my perception at the time was that that was likely more like a commodity market in which there was probably more purchasing power on the part of the large purchasers, but not the same ability to raise prices on the up-side to small purchasers that prevailed on the brand name side.
Q. I'd like to focus you just for a minute, before we turn to a specific document, about a particular generic drug. I think you mentioned commodities. Are you familiar with sodium saline solution?
A. Yes.
Q. It's a bag of salt water, essentially. Correct?
A. That's correct.
Q. Would you agree with me that you can't

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get much more commoditized in a bag of salt water in the drug market?
A. The only quibble I would provide to that question is I never really thought of it as classically being part of the pharmaceutical market. It was such a -- it was really a hospital supply kind of market. It was such a standard product that even though it was FDA regulated and -- and sterility issues were so forth, it tended to be -- hospitals tend to stock it, for example, in sterile supplies, put it on their cost report as part of sterile supplies rather than through their pharmacies.
Q. But a home infusion provider reimbursed under Part B, for example, might be reimbursed for sodium saline solution.
Was that your understanding in '97?
MS. BROOKER: Objection. Form.
A. Yes, but whether that was as a supply or a drug, I honestly couldn't tell you. I would have thought of it as a supply.
Q. Turning to the market of it, whether we

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call it a drug or -- or a supply, did you have an understanding, in 1997, of what the market would look like for a product such as sodium saline solution?
MS. BROOKER: Objection. Form.
MR. BREEN: Objection. Form.
A. Yes, I did.
Q. And what was your understanding?
A. Well, I actually -- in the 1980s, I believe, when I was first becoming involved in some of these issues in health care economics was the first development of hospital group purchasing operations, and I recall -- and the first widespread circulation of the -- of "Modern Healthcare," the magazine, and I recall monthly headlines in "Modern Healthcare" about group purchasing operations being -- achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies.
So, my perception was that on the supply market, which, again, I understood and still would contend is actually a separate market

from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.

Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay $10 per bag, and a large purchaser who bought a very large volume would pay less than a dollar?

MS. BROOKER: Objection. Form.

A. I would not have been surprised.

Q. Okay. So, to that extent that -- President Clinton referring to a 10-to-1 ratio is something that would be consistent with your understanding of that particular market. Correct?

MS. BROOKER: Objection. Form.

Q. I'm sorry. You have to verbalize.

A. Again, I would have thought that market was a subset of the supplies market rather than the drug market.

Q. That was my question. But you would have distinguished between the drug market, where 10-to-1 would not -- you would not expect to see. Correct?

A. That's correct.

Q. And the supply market, where sodium saline solution would be found, where there could be a huge variation between a small purchaser purchasing at list price and a very large purchaser purchasing at 99 percent off of list price?

MS. BROOKER: Objection. Form.

A. I would have made such a distinction, and I would not have been surprised to see those sorts of differentials of the supply market.

Q. And in between the commodities supply market of sodium saline and the patent-protected market of a brand name drug, would you expect generic drugs to be somewhere between those two extremes?

MS. BROOKER: Objection. Form.

MR. BREEN: Objection. Form.

A. That would be a question I never thought about before today. But today I would say that we always made the distinction between -- between drugs and -- and supplies. And, again, I would fall back on the Medicare green eyeshade distinction between what's sterile supplies and what's pharmacy.

MR. COOK: Let's take a break.

THE VIDEOGRAPHER: The time is 11:28 a.m. We're going off the record, concluding Tape No. 2 in the deposition of Dr. Bruce Vladeck in the matter of In re Pharmaceutical Average Wholesale Price Litigation.

(Recess taken.)

THE VIDEOGRAPHER: The time is 11:46 a.m. We're going back on the record, starting Tape No. 3 of the deposition of Dr. Bruce Vladeck in the matter of In re Pharmaceutical Average Wholesale Price Litigation.

Q. Doctor, based upon what we were talking about just before the break, would it be fair to say that while you were administrator of HCFA,

you did not understand published average wholesale price to be the average of prices at which wholesalers were selling their drugs to their customers?

A. It would -- it would be fair to say that I did not believe it was, in fact, an empirical estimate, that rather it was a -- an amount reported by the manufacturer to -- of the compendium compilers or whatever, yes.

Q. And, again, akin to a sticker price?

A. That's correct.

Q. Where did you get that understanding?

A. I believe that was probably what my staff explained to me when I first encountered the concept sometime after I took office.

Q. Do you recall anybody within HCFA who was under the belief that average wholesale price was an average of prices at which wholesalers sold drugs to customers?

MS. BROOKER: Object to form. And I would just instruct the witness, just, you know, be mindful of not disclosing deliberations,

EXHIBIT BH

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

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In re: PHARMACEUTICALS INDUSTRY	:	MDL No. 1456
AVERAGE WHOLESALE PRICE	:	Civil Action
LITIGATION	:	01-CV-12257-PBS
_____:		
THIS DOCUMENT RELATES TO:	:	Judge Patti B.
United States of America, ex	:	Saris
rel. Ven-a-Care of the Florida	:	
Keys, Inc.,	:	
vs.	:	Chief Magistrate
ABBOTT LABORATORIES, INC.,	:	Judge Marianne
No. 06-11337-PBS	:	B. Bowler

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Baltimore, Maryland

Thursday, October 11, 2007

Continued Videotaped Deposition of ROBERT NIEMANN

Volume 2

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this transmittal is implementation of the new payment limit for drugs and biologicals. Do you recognize Exhibit Abbott 202?
A. Vaguely, yes.
Q. If you turn to the second page, you're identified as the contact person for this program memorandum, correct?
A. That's me.
Q. What do you recognize transmittal number AB-97-25 to be?
A. Well, a program memorandum was an instruction to our carriers who administer the Medicare program.
Q. Did you draft Exhibit Abbott 202?
A. I would have at least drafted the first iteration of it.
Q. What's the purpose of this particular program memorandum?
A. Well, that's in the first sentence there. The purpose is to furnish the carriers and intermediaries with instructions needed to implement Section 4556 of the BBA of 1997.

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Q. And so as I understand it, Congress spoke to the agency and told the agency to pay at 95 percent of AWP, correct?
A. Yes.
Q. And the agency in turn spoke to the carriers and gave the carriers more detailed instructions about how to implement that statutory obligation, correct?
A. Yes.
Q. What did you understand Congress to be referring to in Exhibit Abbott 201 when Congress referred to 95 percent of the average wholesale price?
A. I guess -- I don't remember -- I don't remember the content of any conversations I had with Congressional staffers that would inform on the answer to that question, but whatever they had in mind, this instruction here seems to state that same language that we've discussed ad nauseam before now as reflected in sources such as the Red Book, Blue Book or Medispan.
Q. If you look at Exhibit Abbott 201, on

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the third page of Exhibit Abbott 201 is the actual statutory language. It's in the first paragraph at the top of the third page. It indicates that the drug or biological be payable at an amount equal to 95 percent of the average wholesale price, correct?
A. Equal to 95 percent of the average wholesale price.
Q. That term, the average wholesale price, it's in lower case, correct? It's not capitalized, right?
A. Right.
Q. It doesn't refer to as published in compendia, or does it?
A. It doesn't.
Q. Leaving aside for a minute what the agency instructed its carriers to do, how did -- what did you understand Congress to be referring to with that language?
A. I guess -- I guess I can't leave that other document aside. That's really the only thing I can -- I can remember, is the agency's

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interpretation of what that referred to.
Q. Again, we'll get to the agency's interpretation in a minute, but your job was focused quite tightly on the portion of Medicare Part B that was being affected by this particular statute, correct?
A. Yes.
Q. Were you involved in discussions with Congress regarding this particular statutory change?
A. I think so.
Q. Do you recall whether you learned of the passage of this bill very soon after it was enacted?
A. I think our legislative people had most of the contact, and they probably would have told me.
Q. You were having discussions within the agency and outside the agency about the fact that Congress was considering a 95 percent of AWP statute in the Balanced Budget Act of 1997, correct?

EXHIBIT BI

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	:	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	:	CIVIL ACTION:
PRICE LITIGATION	:	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:	
U.S. ex rel. Ven-a-Care of	:	Judge Patti B. Saris
the Florida Keys, Inc. v.	:	
Abbott Laboratories, Inc.,	:	Chief Magistrate
No. 06-CV-11337-PBS	:	Judge Marianne B.
- - - - - - - - - - - - - - - -x		Bowler

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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STATE OF ALABAMA,	:	
Plaintiff,	:	
vs.	:	Case No.: CV-05-219
ABBOTT LABORATORIES, INC.,	:	Judge Charles Price
et al.,	:	
Defendants.	:	

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administrators, and since that was a small component in terms of number of people, memos were prepared by the bureau and went through the associate administrator, so there's a place for the associate administrator to initial that after it had been signed by the bureau director. I have no idea whether this was actually signed, by the way. There's no date on it, there's no signature.
Q. In 1988, you reported to Ms. Buto, and did Tony Lovecchio report to you?
A. Yes.
Q. On the first page of the bottom where it says "Revised, Tony" --
A. Yes.
Q. Do you recognize that handwriting?
A. No. It's not Tony's.
Q. Okay. You'll see that there are -- well, first of all, the purpose of this memo appears to be to get approval for a letter to be sent to the State of Oklahoma with respect to its state Medicaid plan, correct?
A. That's what it appears to be.

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Q. There is an attachment at tab A, report of issues and background. If this memo, the report and the attached draft letter were drafted by Tony Lovecchio for Ms. Buto's signature for distribution to the administrator through the associate administrator for program development, is that something that you would have been involved in reviewing?
A. Normally if I had been there when this came through my office, I would have signed off on it.
Q. And how within HCFA would your signing off on a document normally be recorded?
A. One copy of this would be on yellow tissue paper. At the bottom, there would be a box that would have -- would contain individual boxes for as many as nine signatures. Normally the person who wrote it and branch chief, division director and I would have signed off on that file box before it went to Ms. Buto, who would have signed the memo and the file box.
Q. If you look at the first page of tab A,

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it's a document entitled "Report on Oklahoma State Plan Amendment 87-18." You'll notice at the very bottom a sentence beginning with, "Our position," states that, "Our position is that AWP is inflated and overstates the price the providers actually pay for drugs," and then lists various things upon which that position was based. Do you see that?
A. Yes.
Q. Is it your understanding that it was the position of HCFA in 1988 that AWP was inflated and overstated the price that providers actually paid for drugs?
MR. GOBENA: Object to the form.
A. I have no idea what HCFA's position was. I believe that was our position within payment policy.
Q. Was it the position within payment policy that AWP was inflated and overstated the price that providers actually paid for drugs?
MR. BREEN: Objection to form.
MR. GOBENA: Join.
A. Yes, by some percentage, and it of course

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varied by drug and --
Q. And because -- well, let me strike that. Within HCFA, were you able to determine with any precision which drugs varied from AWP by which percentage?
A. No.
MR. GOBENA: Object to the form.
BY MR. COOK:
Q. And so is it fair to say that AWP was not a reliable indicator of actual provider acquisition cost?
MR. GOBENA: Object to the form.
A. It depends upon the drug and the dosage and who purchases it and in what volume.
Q. If you could turn to what I gave you and what's been marked as Exhibit Abbott 117, can you tell me -- do you know who Don Hearn, chief of state operations branch, is?
A. No. I believe at the time, he was an employee of the Dallas regional -- or the -- yes, the Dallas regional office.
MR. COOK: I'll ask the court reporter to

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(captions continue on following pages)

Videotaped deposition of CHARLES R. BOOTH

Volume II

Washington, D.C.

Monday, October 29, 2007

10:00 a.m.

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A. And we were the ones who would be setting the initial changes in price were they to be made.
Q. To your knowledge did anybody else within the Office of Payment Policy have any expectation between what acquisition costs should be and what AWPs should be?
MR. GOBENA: Objection, form.
A. I have no idea.
Q. And so certainly nobody expressed to you an expectation that there would be some relationship between acquisition cost and AWP?
MR. GOBENA: Objection, form.
A. I certainly don't remember any.
Q. Did that change over time?
A. No.
Q. And that would mean that your expectations -- your lack of expectations didn't change over time, correct?
A. I had no idea what the relationship would be between the cost to a physician or a pharmacist of a particular drug and AWP.
Q. Were you involved at all in the attempt

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to use surveys to establish an estimated acquisition cost after the promulgation of the regulations in November of 1991?
A. Yes.
Q. What was your involvement?
A. We reviewed some of the drugs that we thought would be appropriate for surveys. And I reviewed a proposed survey instrument.
Q. We'll look at some documents relating to this. But to fast forward a little bit, the surveys were never implemented as I recall, correct?
A. That is correct.
Q. Why were they never implemented?
A. Because we did not get approval from the Office of Management and Budget to conduct them.
Q. Do you know why the Office of Management and Budget did not approve the surveys?
MR. GOBENA: Objection, form.
A. I do not.
Q. Do you know who at the Office of Management and Budget considered or participated in any considerations relating to these surveys?

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A. No.
MR. COOK: Let me hand you what I'll ask the court reporter to mark as Exhibit Abbott 361.
(Exhibit Abbott 361 was marked for identification.)
BY MR. COOK:
Q. While you're taking a look at this one-page document, Mr. Booth, for the record I'll note that this is a February 25, 1994 memorandum. It appears to be to you from Stuart Streimer. Do you recall this memorandum, Mr. Booth?
A. No, sir.
Q. Who is Stuart Streimer?
A. Well, at the time the note was written Stuart Streimer was the director of one of the offices in the Bureau of Program Operations, specifically the one that wrote operating procedures for the Medicare program.
Q. If you see in the first paragraph it appears that Mr. Streimer is thanking you for the opportunity to review and comment on draft

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instructions for pricing drugs. Do you recall Mr. Streimer being involved at all in the attempt to establish surveys to establish estimated acquisition costs?
A. No. I don't recall.
Q. In the next paragraph Mr. Streimer appears to express a concern that the data is being extracted exclusively from physicians and states that the small select sample "may not adequately reflect the global picture of drug acquisitions costs."
Did you recall those concerns being involved in setting up the surveys for estimated acquisition cost?
A. I don't recall.
Q. Do you know whether those concerns were addressed at all in establishing the surveys?
A. Well, you know, we never really finished the survey instrument. So no, I don't recall.
Q. And then in the next paragraph would you agree with me that this discusses, at a high level of generality, how physicians purchased their drugs,

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best source of information about how much a drug costs, correct?
A. That's what the memo says.
Q. And what did you identify as the best source of information about how much that drug costs?
A. The invoice to the physician from a supplier.
Q. And in this memorandum did you advise the associate regional administrators that there would be the possibility that the invoice might show discounts to the purchase of the drug?
A. Yes.
Q. Did you also advise the administrators that discounts received at the end of the year might not be reflected on the invoice?
A. Yes.
Q. In this memorandum when you refer to discounts, Mr. Booth, what were you referring to discounts being from?
A. I believe this refers to discounts from the invoice price.

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Q. So if I were a physician and I received a 10 percent discount and my invoice showed that instead of paying $10 I paid $9, what was your understanding of what the amount was that was the benchmark from which the physician would receive a discount?
MR. GOBENA: Objection, form.
A. If the discount is shown on the invoice then that's not an issue. It's when the discount is not shown on the invoice and is shown somewhere else we were advising carriers to be on the lookout for.
Q. But am I correct that this memorandum reflects an understanding that for physicians there would be a list price, a published list price, and that they may, in certain circumstances, receive a discount off of that list price?
MR. GOBENA: Objection, form.
A. I think your inference is incorrect.
Q. Okay. What was the understanding of the amount from which physicians would receive a discount on the invoice?
A. I think this suggests that it might vary

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from supplier to supplier and perhaps invoice to invoice.
Q. The amount of the discount, correct?
MR. WINGET-HERNANDEZ: Objection, form.
MR. GOBENA: Same objection.
A. The invoice might show a list price and might not. It might show a discount and might not. Discount might be taken then, might be taken later. We were advising carriers to be on the lookout to determine as closely as possible what the actual acquisition cost was without relying necessarily on a single piece of paper.
Q. If you could turn to the second page of this memorandum, under additional issues there's a paragraph that begins with "Determination of AWP." And the first sentence of that, I'll just read it for the record. "To determine the AWP, calculate the median price of the generic form of the most frequently administered dosage of the drug as reflected in sources such as the Red Book, Blue Book or Medi-Span."
Is that consistent with your

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understanding in 1994 that the AWP was a published price that could be found in these compendia?
MR. GOBENA: Objection, form.
A. Yes. I believe we consistently advised carriers that these were the most frequently used published sources for AWP.
Q. If you look at the very last paragraph on that page it discusses payment per dose for single dose vials. Do you see that paragraph?
A. Yes.
Q. I'd like to focus just on the first three words of the third line. In advising carriers how to deal with payment per dose for single dose vials your memo refers to the cost or AWP of the vial. Do you see that?
A. Yes.
Q. In that sentence and throughout this memo a distinction appears to have been drawn between the cost of a drug and the average wholesale price of the drug. Do you recall that distinction between cost and price being one that was generally drawn when discussing drugs in this context within CMS?

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actually paid by providers."
Do you see that?
A. Yes, I do.
Q. And is that a statement that generally comports with your understanding of what HCFA had done up until then?
MR. HAVILAND: Objection.
MR. BATES: Objection.
MR. GOBENA: Object to the form.
A. In 1975 there was no HCFA. And the Medicaid program was being administered by the Social Rehabilitative Services arm of the Department of Health Education and Welfare. I have no understanding of what the department cautioned as early as 1975.
I came to realize, as I indicated earlier, sometime in I believe 1985 or early 1986 that AWPs were not the prices being paid by physicians and pharmacists for drugs.
Q. When you came to that realization in 1985 or 1986, did you undertake any steps to change the way states were reimbursing for drugs?

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A. Well, as I indicated earlier we stopped approving state plans that used AWP as the mechanism for pricing drugs. We didn't approve state plans that suggested that AWP was their payment methodology.
Q. And the reason is, just so I'm clear, is because you as the director of Office of Payment Policy had realized AWP did not reflect actual acquisition costs?
A. Well, I think it's wider than a personal realization on the part of the director of the Office of Payment Policy. But clearly, you know, I recognized that to be the case.
Q. When you say it was wider, can you explain what you mean by that?
A. Well, again, the individuals who adjudicated the payment issues for state plans on my staff had clearly come to this position before I realized that it was an issue.
Q. Do you know when they came to that conclusion?
A. I do not.

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Q. Did you have discussions with them about the conclusions that they were drawing from their analysis?
A. I believe there was one briefing sometime in late 1985 about it. But that was more to acquaint me with the issue than discuss any policy changes.
Q. The second sentence of that third paragraph of Exhibit J&J 002 talks about policy issuances. I guess I'll read the whole sentence. It says, "This has been reiterated by the Department over the years to State Medicaid agencies through policy issuances which have stated that the estimated acquisition cost or EAC should be 'As close as feasible to price generally and currently paid by providers.'"
I guess my question is, can you tell me about what are policy issuances in this sentence?
MR. GOBENA: Objection to form.
MR. HAVILAND: Same objection.
A. I don't remember what the policy issuances mechanism was for Medicaid state agencies.

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I believe that there were a series of numbered letters that went out to the states.
Q. And what's a numbered letter?
A. If you issue ten policy statements during the year the first one is 85-1. The second one is 85-2 and so forth.
Q. Do you recall -- so you said there were a number of these numbered letters that went out to the states?
A. No. I believe that was the way policies were issued to state agencies during that period. I don't know how many letters were issued.
Q. Okay. And then again turning to the letter in that paragraph it continues to discuss an OIG report to Congress and to HCFA recommending action to reduce inflated Medicaid drug reimbursement and it explains how OIG conducted intensive survey samples in six states.
Do you recollect OIG conducting those survey samples?
A. No, I do not.
Q. The last sentence says, "HCFA acceptance

MR. GOBENA: Object to the form.
A. It was my understanding that physicians were paying less for many drugs than they were receiving in payment.
Q. You answered some questions from a number of attorneys, including Mr. Merkl most recently, about your understanding about what AWP referred to. Do you recall those questions?
A. Yes.
Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?
A. AWP was what the manufacturers chose to put in the compendia.
Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?
A. No.
MR. GOBENA: Object to the form.
Q. At any time were you ever fooled into believing that average wholesale price somehow was the same thing as acquisition cost?

MR. GOBENA: Objection to the form.
MR. WINGET-HERNANDEZ: Objection.
A. Was that a leading question?
Q. Yes, sir.
A. Fine.
I did not believe that there was a relationship to any great extent between acquisition costs and AWP.
MR. MERKL: I have no more questions.
MR. GOBENA: Anyone else? Or are we done?
THE VIDEOGRAPHER: This deposition concludes at 4:12:15 and consists of five tapes.
(Whereupon, at 4:12 p.m. the deposition was adjourned.)
* * * * *

_____
SIGNATURE OF THE WITNESS

Subscribed and sworn to and before me
this _____ day of _____, 20____.

_____
Notary Public

EXHIBIT BJ

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	) CIVIL ACTION
PRICE LITIGATION	) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)
U.S. ex rel. Ven-a-Care of	) Judge Patti B.
the Florida Keys, Inc.	) Saris
v.	) Chief Magistrate
Abbott Laboratories, Inc.,	) Judge Marianne B.
No. 06-CV-11337-PBS	) Bowler

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(captions continue on following pages)

Videotaped deposition of Kathleen Buto

Volume I

Washington, D.C.

Wednesday, September 12, 2007

9:00 a.m.

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forth in section 1861(S)(2) of the act."
And then the next paragraph states "We considered the following options for paying for drugs under the fee schedule: Option 1, establish a fee schedule amount for each drug." And option 2 was "Bundle the payment for the drug into payment for the visit or consultation service."
3, "Make a separate payment for a drug and leave the pricing of the drug to each carrier." Option 4, "Make a separate payment for a drug but require a consistent method in pricing to be used by the carriers." Correct?
A. Yes.
Q. And then below I believe the comments state that option 1 was rejected at least for the time being because it was not practical; is that correct?
A. Right.
Q. And do you recall that?
A. Yes.
Q. And there's reference to considering

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the issue in the future?
A. Mm-hmm.
Q. Do you recall whether that was considered in the future?
A. I don't think so.
Q. Do you know why not?
A. The press of other business.
Q. Option 2, "Bundle the payment for the drug into the payment for the visit or consultation service," was that --
A. Well, actually, let me just amend what I just said. I think the other reason was we were going down a different path in drug reimbursement looking to do at a lower percentage off AWP. So we decided -- we sort of went down that path and didn't go down the other path of trying to compute individual prices for a whole fee schedule for all drugs that Medicare uses at all dosing levels. Just a laborious, labor-intensive effort.
Q. In the paragraph under option 4, that next paragraph that starts "We believe," the last

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sentence states "Also we are proposing that we will instruct all carriers to base payment for drugs on 85 percent of the national average wholesale price of the drug (as published in the Red Book in and similar price listings), but we welcome comments regarding the appropriate discount."
Do you recall receiving comments regarding the appropriate discount?
A. I don't. But I am guessing there were comments.
Q. Who was responsible for reviewing the public comments that came in to your office as recognition --
A. Oh. We had a --
Q. For drugs?
A. Well, it's for everything. There was a regulation staff and the regulation staff has a fairly systematic way of bringing comments in, as many as forty to ninety thousand comments on certain regulations. So they catalogue them. Log them in, date stamp them.

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And they try to categorize them by category in the regulation because different regulations have different staff involvement. So you've got to group them so that the staff who has to look at them has a binder like that (indicating) of the comments they have to review. And that staff, the regulation staff, is the one that pulls all the comments together.
I believe the staff was headed up by a woman named Sue Brown, B-r-o-w-n, at the time this regulation was done.
Q. In the next paragraph about three-fourths of the way down there's a sentence that starts with "moreover." Do you see that?
A. No.
Q. I think it's the third, fourth full sentence under the Medicare policy paragraph.
A. Fifth from the bottom?
Q. Second-to-last sentence from the bottom in the paragraph. "Moreover." It states "Moreover, we are proposing for very high volume drugs the payment for the drug would be limited

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to the lower of the estimated acquisition cost of the drug as determined by us and specified in instructions to carriers or 85 percent of the national average wholesale price for the drug."
A. Right.
Q. What did you mean when you say "national average wholesale price for the drug"?
A. AWP.
Q. As reflected in Red Book or a similar --
A. Yes, or some other resource.
Q. Why did you propose this estimated acquisition cost option for very high volume drugs?
A. Because we didn't think that Red Book even a 15 percent discount was an accurate acquisition cost. We wanted to do a survey, actually look at the acquisition cost.
Q. You believed that for some drugs the discount might be greater than 15 percent?
A. Yes. And we were -- as you can see, we were looking for the low hanging fruit. We were

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looking for the high volume drugs where Medicare was probably a dominant payor.
(Exhibit Abbott 299 was marked for identification.)
BY MR. TORBORG:
Q. For the record, what I've marked as Exhibit Abbott 299 is is a document that was I believe collected in counsel's review of public comments maintained by HCFA for this proposed regulation. This particular one comes from the National Medical Care, Inc. organization.
A. Right.
Q. I have a number of questions for you on this document, but let me start off with a few to start off with. Are you familiar with National Medical Care?
A. Yes.
Q. And what kind of an organization are they?
A. They run for-profit dialysis centers.
Q. If you would go to the third page of the document, the last paragraph, NMC wrote "As a

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technical matter it should be noted that while in the discussion of the proposal it is clear that HCFA proposes to pay 85 percent of AWP of a drug" -- and this is in italics -- "as published in redbook" -- end italics -- "the actual proposed regulatory language is '85 percent of the national average wholesale price of the drug" -- and then in italics -- "as determined by HCFA.'
"In the first case, AWP is a category of data of questionable relationship to reality contained in the particular published source. In the second, AWP is empirically determined by HCFA and might in fact be an accurate reflection of prices paid. But certainly HCFA does not propose to pay 85 percent of the actual average acquisition cost - a policy which would result in none of the affected drugs being provided. This inconsistency needs to be eliminated."
And if you look back at the document I just showed you, the proposed legislation, on the last page of that exhibit, page 137 at the top, in fact in the payment rule they did -- that is

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how you defined AWP in that proposed regulation, correct? I'm under 42 C.F.R. section 415.34, section B, payment rule.
A. Okay.
Q. It states "Except as specified in paragraph D of this section, payment for drugs furnished incident to a physician's service is limited to 85 percent of the national average wholesale price of the drug as determined by HCFA," correct?
A. (Nods head).
Q. And that was the language that NMC had pointed out to you as being --
A. Yes.
(Exhibit Abbott 300 was marked for identification.)
MR. DRAYCOTT: With this document we reach another milestone?
MR. TORBORG: Yes. Exhibit Abbott 300.
BY MR. TORBORG:
Q. Ms. Buto, what we've marked as Exhibit Abbott 300 is another comment that was obtained

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Q. And you indicated -- and HCFA indicated in its rule that they received many comments on this issue, correct?
A. Correct.
Q. And subsequent to those comments HCFA changed its rule in some ways that included paying the lower of EAC, estimated acquisition cost, or 100 percent of average wholesale price, correct?
A. Right.
Q. Why did HCFA change the AWP-based formula from 85 percent of AWP to 100 percent of AWP?
A. And I think they use a different terminology, don't they, or we did at the time. So they didn't seem to use the same term, although later -- but why did they go from one proposed policy to the final policy?
Q. Yes.
A. Let me answer that. Based on comments and based on a lot of concern that was raised -- and I think you picked out a couple of the

Page 305

comments, but they weren't the only ones -- that pointed to the fact that on the one hand HCFA seemed to be saying there was going to be a national -- I've forgotten what the term is -- but a national average wholesale price didn't refer to published average wholesale price. And that in describing what HCFA planned to do it was clear HCFA was going to try to get accurate price data.

And they went on to say if HCFA gets accurate price data if you pay at 85 percent of an accurate price you're going to be systematically underpaying. So they pushed back on that and there was a lot of logic to their comment, that if you're going to pay accurately and then lower the price to less than a 100 percent there's an issue.

So the compromise that was come up with was the final rule position, which is 100 percent. However, that would be sort of the lower of that or the acquisition cost and that the -- or the actual acquisition cost. And that would

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be based on surveys.
Q. But if we used the average wholesale price method it would be based on what was published in the Red Book, correct?
A. Yes. That was made clear later in one of the other documents, that it was based on the published. But in the -- I think in the original description they didn't refer to published.
Q. Why did HCFA remove the 15 percent discount from AWP?
A. Again, because HCFA was concerned that it conveyed -- what HCFA was really after was getting an accurate reimbursement level or price -- okay? -- what price should reimbursement be set at. And the concern was that what we really wanted to convey there is that we were going to try to find out what that was.

And so the mechanism was getting or conducting surveys of actual acquisition costs and that the AWP was the fallback. And actually high-volume drugs were going to be a special target for the surveys of actual acquisition

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costs because of the greater impact on Medicare.
Q. Did some of the comments -- if we go back to page 56 of the rule, the second paragraph on payment for drugs states "Also a number of comments from the oncologists indicated that we should use an add-on to cover the cost of breakage, wastage, shelf life limitations and inventory costs associated with chemotherapy agents.

"Some commentators also suggested that this add-on payment was needed to account for shortfalls in chemotherapy administration payments. Without adequate compensation, commenters suggested, many physicians would performed the service in hospital outpatient departments at substantially higher costs.

"Also some commenters suggested that physicians would refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case the drugs would not be covered by Medicare since

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
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U.S. ex rel. Ven-a-Care of	)	Judge Patti B.
the Florida Keys, Inc.	)	Saris
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(captions continue on following pages)

Videotaped deposition of Kathleen Buto

Volume II

Washington, D.C.

Thursday, September 13, 2007

9:00 a.m.

submitted a plan based upon solely AWP you would have expected that HCFA would have also disapproved those plans, right?
MR. DRAYCOTT: Objection.
A. I guess the nuance to me is if it's AWP minus 40 percent would I have disapproved it? I don't know. It really had to do with AWP as a basis and AWP unmodified.
Q. Fair enough. Now, let's go to 1991. And I want to turn your attention to the proposed rule that you submitted in 1991 or that HCFA submitted regarding Medicare reimbursement.
A. Yes.
Q. And as you recall HCFA submitted a proposed rule that it would be 85 percent of AWP, correct?
A. Correct.
Q. But that wasn't adopted, right?
A. Right.
Q. And what ended up occurring is that HCFA or ultimately Congress adopted 100 percent AWP reimbursement for Medicare drugs or actual

acquisition cost, right?
A. It wasn't Congress now. It was HCFA in the final rule.
Q. That's right. Now, there's no doubt that as of 1991 HCFA knew that unmodified AWP, a hundred percent AWP, did not represent actual acquisition cost, right?
A. Yes.
Q. And there was no doubt that in 1991 HCFA knew that there was no predictable relationship between AWP and actual acquisition cost, right?
A. Based on the surveys from the IG, that's correct. That was our belief. Again, we didn't have independent data.
Q. Right. That was your belief at that time, right?
A. That's correct.
Q. And it's fair to say that when HCFA adopted the final rule in 1991 paying 100 percent AWP, it knew that if it paid 100 percent AWP it was not paying actual acquisition cost, right?

MR. DRAYCOTT: Objection.
A. We -- that's correct. We did not intend for that to be the sole method, as you know.
Q. You didn't spend to pay 100 percent AWP forever because you intended to do the actual surveys of acquisition costs, right?
A. That's correct.
Q. But that never happened, right?
A. That's also correct.
MR. GORTNER: I have no further questions. Thank you for your time.
THE WITNESS: Thank you.
MR. DRAYCOTT: Unless I hear an objection right now I'm assuming we're concluded. With the reservation by Mr. Torborg stated earlier.
THE VIDEOGRAPHER: This concludes volume 2 tape 3 in the deposition of Kathleen Buto. The deposition concludes at 12:40 p.m.
(Whereupon, at 12:40 p.m. the deposition was adjourned.)

_____
KATHLEEN BUTO

Subscribed and sworn to and before me this _____ day of _____, 20____.

_____
Notary Public

EXHIBIT BK

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
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No. 06-CV-11337-PBS	)	Bowler

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Videotaped deposition of ELIZABETH RICHTER

Washington, D.C.

Friday, December 7, 2007

9:00 a.m.

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average price being paid by customers was, you would agree with me that if that had been Congress' command to the agency the agency would have attempted to implement that command, correct?
MR. DRAYCOTT: Objection. You can answer.
A. If they had explicitly instructed us to survey -- I'm sorry. I'm not --
Q. Let me ask it in a different way. Do you have Judge Saris' opinion there in front of you?
A. I do.
Q. What exhibit number is that?
A. Exhibit Abbott 389.
Q. Exhibit Abbott 389. Do you see at the bottom of page 39 Judge Saris says the court concludes the statutory term AWP to mean "The average price at which wholesalers sell drugs to their customers, including physicians and pharmacies."
A. Yes.

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Q. If Congress had instructed CMS to pay 95 percent of "The average price at which wholesalers sell drugs to their customers, including physicians and pharmacies," do you have any reason to believe that CMS would have implemented that statutory command by looking up AWPs in the compendia?
MR. DRAYCOTT: Objection. You can answer.
A. I think that's what HCFA did. And I can't say other than by the information in the regulations and the preambles -- I can't say what the correction was. And it seems to me that we make decisions every day about how to implement something based on the resources available to implement that program and the other commitments of the agency. And we don't live in a world of perfect information. And so the decision was made to use the compendia AWPs.
Q. You'll agree with me that the agency implemented the statute as it understood the statute -- in good faith, what it understood the

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statute to mean, right?
A. Yes.
Q. And you'll agree with me that from Louis B. Hays through Dr. Vladek through Ms. Min DeParle through Mr. Scully, through the information you've looked at no administrator thought that published AWPs represented the average price at which wholesalers sold drugs to their customers, correct?
MR. DRAYCOTT: Objection.
A. That is what their testimony says, yes. But again, without seeing the full context. But yes, that's what it says.
Q. As a fair to assume that if Congress had never used the word average wholesale price, that if Congress had said, Dr. Vladek, Ms. DeParle, I want you to pay providers the average price at which wholesalers sell drugs to their customers, that the last place they would have looked would have been in compendia for AWPs?
MR. DRAYCOTT: Objection.
A. I have no -- I can't step in their

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shoes and figure out where they would have looked or not looked.
Q. Vaccines are paid based upon the current published AWPs, correct?
A. Yes.
Q. Currently is the agency undertaking any effort to determine what the average price is at which wholesalers are selling drugs to their customers other than by looking it up in compendia?
MR. DRAYCOTT: Objection. You can answer.
A. Not to my knowledge, no.
Q. So do you understand today to be the statutory command to pay average wholesale price to be satisfied by looking it up in the compendia?
MR. DRAYCOTT: Objection.
A. Yes.
Q. Do you understand that Congress had ordered you to pay the average price at which wholesalers are selling vaccines to their

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which pharmaceutical firms and wholesalers are selling drugs to retail customers in the marketplace?
MR. DRAYCOTT: Objection.
A. I think I believe -- sorry. I believe that it is possible that certain AWPs represent that. But I don't believe that that is typical or uniform. Or frequent even.
Q. Can you give me the name of a drug for which that is true?
A. No. But I believe if you went back to the drugs that we accepted from the 85 percent in 2004, I'm not sure that I would say exactly that it was a precise mathematical relationship, but there were certainly at least one or two drugs where it was a very close relationship, and where certainly some customers could have paid the --
Q. And that would be one or two drugs out of how many?
A. It's about 400. But that's a rough estimate.
Q. So in your job you will at times refer

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to the AWP for a drug, right?
A. Yes.
Q. The AWP for that drug is $10, right --
A. Yes.
Q. -- or whatever the number is?
What are you referring to when you refer to the AWP for a drug?
MR. DRAYCOTT: Objection.
A. Typically I would be referring to the number that we published on the Exhibit Abbott 420, the set that ended up through whatever was the last number, the set of quarterly updates.
Q. And you would be referring in turn to the number that's published in the compendia, because that's where those numbers came from, correct?
A. I would be referring to a specific AWP as a piece of data. I can't recall referring very often to AWP as a more conceptual idea separate from the data.
Q. And when you say as a piece of data it would be a number, right?

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A. Yes.
Q. And that number would be reflective of what? I mean, data are reflective of the facts in the universe, right?
A. It's helpful. Yes. Certainly the numbers that we report are typically reflective of the information in the published compendia currently.
Q. At any time have you ever referred to the AWP for a number and intended to communicate thereby that the average price at which customers are buying the product is that amount?
A. No.
MR. DRAYCOTT: Objection.
Q. Have you ever known any human being to use AWP in that manner to communicate that concept regarding a particular drug?
MR. DRAYCOTT: Objection.
A. I know that two people agreed to be identified as people who have done that. They did not do it in my presence, to my knowledge.
Q. Mr. Warren testified that in fact he

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had never heard any natural person ever use AWP in that manner. So I guess it would be down to Tom Gustafson, right?
A. Well, what he agreed -- from what you just said he didn't say anything about himself. He talked about other people. But no, I have not heard anybody refer to it in that manner.
Q. Without affect your testimony if you knew that John Warren testified that he would not be an appropriate person to name in response to interrogatory number 7C and 7D?
MR. DRAYCOTT: Objection.
A. If he had said he were not appropriate?
Q. Under oath.
A. Yes. That would affect --
Q. And you don't know whether Tom Gustafson really has ever used AWP in the manner described in paragraph 7C and 7D, correct?
A. Not as a matter of direct hearing.
Q. So you were relying upon representation of counsel to you that it was true when you verified it?

EXHIBIT BL

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

- - -

IN RE: PHARMACEUTICAL	: MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	: CIVIL ACTION:
PRICE LITIGATION	: 01-CV-12257-PBS
	:
THIS DOCUMENT RELATES TO	:
U.S. ex rel. Ven-A-Care of	:
the Florida Keys, Inc. v.	:
Abbott Laboratories, Inc.	:
No. 06-CV-11337-PBS	:

- - -

Videotaped deposition of ROBERT VITO was taken, pursuant to notice, at MORGAN LEWIS & BOCKIUS, LLP, 1701 Market Street, Philadelphia, Pennsylvania, on Tuesday, June 19, 2007, beginning at 9:10 a.m., before M. Kathleen Muino, Professional Shorthand Reporter, Notary Public; Michael Hunterton, Certified Legal Video Specialist, there being present:

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December 1997. The second page indicates it was prepared under your direction. Is that right?
A. That is correct.
Q. Do you recall this report?
A. Yes, I do.
Q. If you go to the section under Background, see the third paragraph, starting with, on January 1; do you see that?
A. Yep.
Q. On January 1, 1998, Medicare Part B will begin -- begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare couriers may -- Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the estimated acquisition cost or the national average wholesale price.
A. Uh-huh.
Q. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in the Red Book and other pricing publications and databases used by the

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pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescriptions drugs.
Did I read that correctly?
A. Yes.
Q. And is that consistent with what your understanding of what the term "AWP" meant in the regulations prior -- that were in effect prior to 1998?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: We -- we understood that the AWP was the information that Medicare used to set the prices and it did come out of the Red Book and the Blue Book.
BY MR. TORBORG:
Q. Did you equate the term "AWP" with the prices that were in Red Book and other price listings?
MR. AZORSKY: Objection to form.
MR. NEAL: Join the objection.
THE WITNESS: When we asked CMS how they

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calculated it, they told us they used the AWP and then if there was a percentage off, then they did that. They told us they took a percentage off of that.
BY MR. TORBORG:
Q. When you used the term "average wholesale price," did you equate it to the prices that were in Red Book and other price listings?
MR. AZORSKY: Objection to the form.
MR. NEAL: Join the objection.
THE WITNESS: I believe it was listed in the Red Book and the Blue Book, yes.
BY MR. TORBORG:
Q. Did you equate it; yes --
MR. AZORSKY: Objection --
BY MR. TORBORG:
Q. -- or no?
MR. AZORSKY: -- to form. Objection to --
THE WITNESS: I -- I -- I -- I --
BY MR. TORBORG:
Q. It's a yes or no question.
MR. AZORSKY: How many times you going to

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ask him?
MR. TORBORG: Until -- until I get an answer.
MR. AZORSKY: You (unintelligible) --
MR. TORBORG: Until I get an answer.
MR. AZORSKY: -- answered ten times.
MR. NEAL: You're -- you're -- you're dissatisfied with --
MR. TORBORG: You can object.
MR. NEAL: You're dissatisfied with the answer, but you've gotten an answer.
MR. TORBORG: Well, I haven't gotten --
MR. NEAL: And the question's --
MR. TORBORG: -- an answer.
MR. NEAL: -- been asked and answered a number of times now. You can ask it again.
BY MR. TORBORG:
Q. It's a yes or no question, Mr. Vito. When you used the term "average wholesale price" in your work at OIG, did you equate it with the prices that were published in Red Book and other price

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listings?
MR. AZORSKY: Objection to form --
MR. NEAL: Objection as to form; asked and answered.
THE WITNESS: I -- I -- I -- I have said that AWP is what the Medicare program based its reimbursement on and they were in the Blue -- Blue Book and Red Book.
BY MR. TORBORG:
Q. Can you answer my question, yes or no?
MR. AZORSKY: Objection to --
BY MR. TORBORG:
Q. And just tell me if you can't. If you can't, that's fine --
MR. AZORSKY: Objection to form.
MR. NEAL: Same objection.
THE WITNESS: I'd like to hear the question one more time.
BY MR. TORBORG:
Q. When you use the term "average wholesale price" or "AWP" in your work at OIG, did you equate it with what was published in Red Book and similar

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price listings?
MR. AZORSKY: Objection to form.
MR. NEAL: Objection as to form.
MR. WINGET-HERNANDEZ: Objection.
THE WITNESS: I -- I -- I -- I -- I guess the answer's yes.
MR. TORBORG: I want to mark this as the next one.
- - -
(Whereupon, Exhibit Abbott 232 was marked for Identification.)
- - -
MR. TORBORG: For the record, what I've marked as Abbott Exhibit 132 bears the Bates -- Exhibit Abbott 232 bears the Bates Nos. HHD042-0018 --
MR. AZORSKY: What's the exhibit number?
MR. TORBORG: Exhibit Abbott 232. -- 20. It is a memo from Mary Beth Clarke at OIG to Shana Olshan at HCFA.
BY MR. TORBORG:
Q. Mr. Vito, this was a document that was

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produced out of the working files for one of the OIG reports that your team worked on, and my question is whether or not you recall this document?
A. I do not recall this document.
Q. And do you see there's a section, Definitions?
A. Yes.
Q. And the first definition is for average wholesale price, AWP in parens, and Ms. Clarke wrote, or at least it's in this memo that she sent: Define -- defines average wholesale price as the pharmaceutical version of manufacturer's list price. It is determined by the manufacturer of a given product and listed in several commercial publications available to the health care community. AWP does not represent the actual average of invoice or purchase price, as very few purchasers actually pay this amount. It is a standard -- it is used as a standard benchmark with negotiated prices often expressed in terms of AWP minus a given percentage.

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Mr. Vito, is this definition of average wholesale price consistent with your understanding of average wholesale price?
MR. AZORSKY: Objection to form.
MR. NEAL: Object to the form.
MR. WINGET-HERNANDEZ: Objection.
THE WITNESS: I -- I -- I don't know that I agree with everything that was said in there.
BY MR. TORBORG:
Q. What aspects of the definition here of average wholesale price are you not sure that you agree with?
A. I -- I don't know that very few purchasers actually pay this amount. Now, I -- I -- I -- I -- I never actually did the -- the reviews, but I guess what we found is that when -- when -- when we looked at the pricing, that it wasn't the price that was available to the physicians and other suppliers, but I don't know -- I don't know the exact percentages of who does -- who's getting it, who's not getting it at that price.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

VOLUME II

IN RE: PHARMACEUTICAL	: MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	: CIVIL ACTION:
PRICE LITIGATION	: 01-CV-12257-PBS
	:
THIS DOCUMENT RELATES TO	:
U.S. ex rel. Ven-A-Care of	:
the Florida Keys, Inc. v.	:
Abbott Laboratories, Inc.	:
No. 06-CV-11337-PBS	:

- - -

Continuation of the videotaped deposition of ROBERT VITO was taken, pursuant to notice, at MORGAN LEWIS & BOCKIUS, LLP, 1701 Market Street, Philadelphia, Pennsylvania, on Wednesday, June 20, 2007, beginning at 8:43 a.m., before M. Kathleen Muino, Professional Shorthand Reporter, Notary Public; Michael Hunterton, Certified Legal Video Specialist, there being present:

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Q. Starting with the -- the first part of the article, in the first column, where the type gets really small, and I'll -- I'll do the favor of reading it --
A. Thank you.
Q. -- because it -- it will be even difficult for me to read it, but I'll do my best.
A. As you get older, it's harder to see.
Q. It's starting to get for me as well. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60 to 90 percent below the so-called average wholesale price, or AWP, used in reimbursement claims.
When did you become aware of the fact that there were -- that generic drugs were being sold to providers at amounts 60 to 90 percent below average wholesale prices?
MR. NEAL: I'll object to the form of the question.
THE WITNESS: I think we became -- I mean, of course, this article pointed it out, but I

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think we also, our work in albuterol sulfate, which is the generic, demonstrated some of those issues as well, as well as some of the other work that we have done here. I believe at this time Leucovorin was also a generic, so there were other generic products that we had seen and seen some pricing variations on.
BY MR. TORBORG:
Q. Do you recall discussions with CMS officials in this time frame about the fact that generic drugs were selling at amounts 60 to 90 percent below the so-called average wholesale prices?
MR. NEAL: Objection as to form.
THE WITNESS: I believe when we issued our reports, the reports pointed out that the products were selling below the -- the AWP and that clearly some of the products were generic.
BY MR. TORBORG:
Q. Did you have a more global discussion about generic drugs in general and what was causing many of those drugs to sell at prices -- for there

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to be such a difference between the actual selling price and average wholesale prices?
MR. NEAL: I'll object to the form and just instruct the --
Instruct you that you can answer that question consistent with my previous instructions not to disclose the substance of any communications that took place at entrance or exit conferences with CMS.
THE WITNESS: Could you restate the question now? I -- I -- I totally --
MR. NEAL: That's a lengthy instruction.
THE WITNESS: Yeah.
MR. NEAL: I apologize.
BY MR. TORBORG:
Q. Did you have any global discussions about generic drugs in general with CMS --
A. Well --
Q. Let me finish.
A. I'm sorry.
Q. -- regarding the fact that there was a -- a larger difference between the actual selling

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prices to providers and the published average wholesale price?
MR. AZORSKY: Object to the form.
MR. NEAL: I object to the form as well.
And you heard my previous instruction.
THE WITNESS: I -- I -- I believe that we -- our reports spoke for themself, in that there were some products that were generics that were -- that had that difference, and there were also some brand name products that had that difference as well. And, again, it was each -- each report stood on its own merit. Albuterol, I think that you showed me we probably did at least -- I saw at least four of the ones that we did, and they were generic drugs, and we were showing what was going on in that.
In addition to that, I -- I -- the excessive Medicare reimbursement report, I believe that also pointed out some problems both with the brand name products and the generic products.
BY MR. TORBORG:
Q. And we'll -- we'll get into the 1997

EXHIBIT BM

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.	:	CIVIL ACTION: 06-CV-11337-PBS

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA, Plaintiff, v. ABBOTT LABORATORIES, INC., et al., Defendants.	:	CASE NO. CV-05-219 JUDGE CHARLES PRICE

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quickly in your work was not necessarily the case, correct?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. I'd like to show you what we've marked before as Exhibit Abbott 051.
MR. TORBORG: For the record, it is a document bearing the Bates Nos. HHD013-2910 through 2911.
BY MR. TORBORG:
Q. The second page is an e-mail from Robert Vito -- I'm sorry -- from Mary Beth Clarke to Robert Vito and Linda Ragone, and it -- and it states in the text: I guess you guys already know the sad truth. The budget package contains a provision for reducing Medicare payments for prescription drugs to 95 percent of AWP. For some reason this makes me feel even -- makes me feel worse than when it was AWP. What a futile attempt! I can't wait to see if CBO even scored it for

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savings.
Do you recall this e-mail?
A. No.
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: No.
BY MR. TORBORG:
Q. Do you recall members of your office being disappointed with the provision in the Balanced Budget Act calling for reimbursement to be tied to AWP?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: No.
BY MR. TORBORG:
Q. Okay. I'd like to hand you what we've marked previously as Exhibit Abbott 052. It bears the Bates Nos. HHD009-0217. It is a memo from Nancy Edwards to Nola Shanks entitled, OIG Final Report, Excessive Medicare Payments for Prescription Drugs, and this was a document that we pulled out of the working files for the '97 report.

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And my question for you is whether or not you've ever seen this document?
A. No.
Q. In the memo, Ms. Edwards wrote: We have reviewed the subject OIG report and have one comment. On Page 10, it states the one option for HCFA to pay for drugs is by estimated acquisition cost, EAC. While this was true prior to January 1, 1998, Section 4556 of the Balanced Budget Act of 1997 has changed the way the Medicare program can pay for drugs and no longer permits EAC. Please refer questions to Robert Niemann.
Do you know who Nancy Edwards is?
A. No.
Q. You ever -- have you ever spoken to her?
A. No.
Q. Do you have an understanding of what EAC means?
A. Estimated acquisition cost.
Q. Okay. Do you have an understanding what that -- what estimated acquisition cost means?
MR. NEAL: Objection as to form.

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You can answer.
THE WITNESS: That however, whether it's a state or Medicare, choose to calculate -- or choose to estimate what providers are paying for drugs.
BY MR. TORBORG:
Q. Do you recall any discussions at OIG about the fact that after the Balanced Budget Act of 1997, Medicare Part B was required to pay AWP and could no longer use EAC?
MR. WINGET-HERNANDEZ: Objection to form.
MR. NEAL: Object to the form.
You can answer.
THE WITNESS: I don't remember any specific conversations about EAC. The conversations would have been just that Medicare is required to pay 95 percent of AWP.
BY MR. TORBORG:
Q. And your understanding of that relates to what was published in Red Book or other price listings, right?
MR. NEAL: Objection as to form.

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You can answer.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. Are you familiar with any law, statute, regulation that requires manufacturers to cause AWPs to be reported for their products in any -- any particular way?
MR. NEAL: Objection as to form.
MS. POLLACK: Object to form.
MR. NEAL: It calls for a legal conclusion.
You can answer.
THE WITNESS: No.
BY MR. TORBORG:
Q. Have you ever had discussions about the fact that there is no law or regulation governing how AWPs should be reported?
MR. NEAL: The same objection.
MR. WINGET-HERNANDEZ: Objection.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. What do you recall about those

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discussions?
MR. NEAL: The same objection.
THE WITNESS: That given how AWPs are being reported, it would be helpful if that's the mode of reimbursement, if it was defined by statute.
BY MR. TORBORG:
Q. Who did you have those discussions with?
A. Robert Vito.
Q. Anyone else?
A. I can't say for sure. I'm -- I'm -- it appeared in the recommendations of several reports, I'm sure, about moving to a reimbursement method that is defined by law, so there would have been other people involved in that.
Q. What efforts did OIG take that you're aware of to define how AWP was reported?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: I -- you know, I'm not aware of -- of any steps we took. We didn't have any conversations with a -- with a compendia as,

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you know, you brought up before.
BY MR. TORBORG:
Q. Did you ever consider steps that could be taken to regulate how AWPs would be reported?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: No.
BY MR. TORBORG:
Q. Do you recall what Mr. Vito -- what any of his words were with respect to the notion that it would be helpful for AWPs to be defined in some way?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: Well, I -- just that the -- the tone was that whatever pricing method is used, it would be helpful if it was defined by law.
BY MR. TORBORG:
Q. Did he explain why that would be helpful?
MR. NEAL: Objection as to form.
THE WITNESS: Because when it's not

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defined by law, the manufacturers reported prices that didn't reflect average wholesale prices.
BY MR. TORBORG:
Q. Are you aware of any communications with manufacturers seeking to have them change the way the AWP reporting structure worked?
MR. NEAL: Objection as to form.
THE WITNESS: I'm not -- I'm not aware of any.
BY MR. TORBORG:
Q. Do you recall any conversations along the lines of, gee, we should call the manufacturers up and ask what they can do to assist us in having AWP reported a certain way?
MR. NEAL: Objection as to form.
THE WITNESS: I'm not aware of any of that.
BY MR. TORBORG:
Q. How hard would it have been to -- to have those conversations with the manufacturers?
MR. NEAL: Objection as to form.
THE WITNESS: Well, for me it would have

EXHIBIT BN

UNITED STATES DISTRICT COURT

OF THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL	:	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	:	CIVIL ACTION
PRICE LITIGATION	:	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:	
U.S. ex rel. Ven-A-Care of	:	Judge Patti B.
The Florida Keys, Inc.,	:	Saris
Plaintiff,	:	
vs.	:	
ABBOTT LABORATORIES, INC.,	:	Chief Magistrate
No. 06-CV-11337-PBS	:	Judge Marianne B.
Defendants.	:	Bowler

VOLUME I

Baltimore, Maryland

Wednesday, September 26, 2007

Videotape Deposition of:

LARRY REED,

the witness, was called for examination by counsel for the Defendants, pursuant to notice, commencing

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A. The minutes would have to be the material I'd make reference to.
Q. And without those minutes, you can't recall whether or not the issue of reliance and average wholesale prices was discussed at the PTAG meetings?
A. There were a number of issues discussed, and to make a definitive statement other than I can't recall, I would have to look at those minutes.
Q. Now, the issue of reliance on average wholesale prices by state Medicaid programs to determine reimbursement has been a hot topic for a number of years; is that fair to say?
MS. MARTINEZ: Objection to form.
THE WITNESS: The issue of payment based on average wholesale price? And by "average wholesale price," you mean the published average wholesale -- what do you mean by "average wholesale price"?
BY MR. TORBORG:
Q. What do you understand the term

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"average wholesale price" to mean?
A. There's a lot of different definitions of it. Average wholesale price typically would simply be the average that a wholesaler sold its product at. There are other definitions that are used within the pharmacy program.
Q. When you use the term average wholesale price, or AWP, what did you mean it to refer to?
MS. MARTINEZ: Objection to form.
MR. HERNANDEZ: Objection to form.
THE WITNESS: Well, that was pretty unanimous.
MS. MARTINEZ: You can answer. We're just objecting to the form of the question.
THE WITNESS: Okay. When we use average wholesale price, generally we will be using average wholesale price as reported by one of the pricing compendia.
BY MR. TORBORG:
Q. Would you agree with me that the issue of reliance on average wholesale prices as reported in the pricing compendia has been a hot

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topic for a number of years?
MS. MARTINEZ: Objection to form.
THE WITNESS: There has been a lot of discussion of average wholesale price as reported by the pricing compendia.
BY MR. TORBORG:
Q. And was this something that you believe was discussed at these Pharmacy Technical Advisory Group meetings?
A. Again, it's possible, but I don't recall.
Q. Well, when we talk about -- when I asked you what was discussed at the meetings, your general recollection was, number one, dispute resolution, number two, payment for drugs.
A. That's correct.
Q. And three, I think you did sort of a catch-all category, right?
A. I don't remember what three was.
Q. Okay. Do you recall anything else that was discussed at the meetings, other than dispute

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resolution or payment for drugs?
A. I do recall that there may be a discussion of new drugs that were coming onto the market, what those -- what those indications might be, some general medical discussion.
Q. And so when you said that the topic of payment for drugs was discussed, what did you mean by that?
A. In general, it might be the -- again, a payment system would be a pretty integral part of the pharmacy program, so some discussion of what a state might be doing, what caution a state may have, but unfortunately I just don't remember if it was a discussion of AWP.
Q. What did you mean when you just referred to there a payment system?
A. States maintain a payment system for pharmacy services that is based on, by federal regulations, estimated acquisition cost.
Q. And in your experience, you know that most states, for the last 10, 15 years and more, have relied on average wholesale prices as

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drugs, both single and multiple source (even if the drug has a MAC)."

Earlier today, Mr. Reed, you made reference to some federal regulations relating to estimated acquisition cost, and I believe you said there was some language you're familiar with about what governs that.

Is this language familiar to you as that language?

A. Parts of it are. Parts of it look to be different than what the current regulations are governing EAC.

MS. MARTINEZ: For the record, I do believe in 1987 there was a slight change in the regulations.

BY MR. TORBORG:

Q. Okay. If I could ask you to go to the top of the third page of the document, it has a number in the upper right-hand corner, 10.193.

The report states, "Within the pharmaceutical industry, AWP means non-discounted list price."

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Mr. Reed, was that consistent with your understanding of what the term "AWP" meant in the pharmaceutical industry?

A. At this point in time? I wasn't working in the program at this point in time.

Q. When you started your position in 1990 on the Medicaid side working on prescription drug issues, was this sentence consistent with your understanding of what the term AWP meant?

A. To qualify that a little bit, if AWP meant the published price in a pricing compendia that the state would have referenced or used in a state plan amendment, then it would be -- it would be my understanding that that AWP would be more than the state should pay for the drug. In other words, AWP should be discounted.

Q. Was it your understanding that AWP referred to a non-discounted list price?

A. It's my understanding that AWP is a price, again, that was reported in the compendia that would be more than what a state would pay for a drug. I'm not quite sure if I would equate

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that list price or what price I would equate that with.

Q. What does the term "list price" mean? Are you familiar with that term in this industry?

A. I've heard it mentioned on many occasions.

Q. What is your understanding of what it means?

A. A list price would be a full price that a purchaser may or may not obtain a drug at.

Q. And you've heard the term AWP referred to or analogized to a sticker price on a car; is that fair to say?

A. I have heard that term, yes.

Q. And have you also heard the term average wholesale price being called ain't what's paid, right?

A. It look a long time to get to that joke, but we finally got there, yeah.

Q. Okay. When did you get to that joke?

A. For you to get to that joke --

Q. Yes.

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A. -- today.

Q. Okay. Yes, it is 3:30.

When did you learn about that?

A. The saying has been around for a long, long time.

Q. If I could ask you to flip forward in this document to the page ending -- or with the number in the upper right-hand corner 10,205, I'd like to read some of the language in the last paragraph and ask you some questions about it.

Actually, why don't you just read that to yourself, and then I'll follow up some --

A. The last paragraph on that page beginning on February 22nd?

Q. Yes --

A. Okay.

Q. -- and then continuing over to the next page.

(A discussion was held off the record.)

THE WITNESS: Just until the top of conclusions on the next page?

UNITED STATES DISTRICT COURT

OF THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL	:	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	:	CIVIL ACTION
PRICE LITIGATION	:	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	:	
U.S. ex rel. Ven-A-Care of	:	Judge Patti B.
The Florida Keys, Inc.,	:	Saris
Plaintiff,	:	
vs.	:	
ABBOTT LABORATORIES, INC.,	:	Chief Magistrate
No. 06-CV-11337-PBS	:	Judge Marianne B.
Defendants.	:	Bowler

VOLUME II

Baltimore, Maryland

Thursday, September 27, 2007

Continued Videotape Deposition of:

LARRY REED,

the witness, was called for examination by counsel for the Defendants, pursuant to notice, commencing

Q. Also I'd like to ask you to go to Bates page ending 667, "Conclusions and Recommendations," for this report.

The first paragraph states, "Based on our review, we have determined that there is a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs is significantly greater for generic drugs than for brand name drugs."

Do you recall becoming aware of that comment in OIG's report?

A. Of this specific comment in this specific report?

Q. Just the general notion, I guess, a broader notion that OIG had found in its work that there was a significantly greater difference in the spread, if you will, between AWP and acquisition costs for generic drugs.

MS. MARTINEZ: Objection, form.

THE WITNESS: That there is a difference between the AWP discount for a brand

and generic drug, yes.

BY MR. TORBORG:

Q. You recall having those -- you recall observing that in the reports or having discussions with HCFA, or what do you recall about that subject?

A. Observing the report, observing that in the reports.

Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs?

MS. MARTINEZ: Objection, form.

MS. POLLACK: Objection, form.

THE WITNESS: I believe we had those discussions.

BY MR. TORBORG:

Q. Who were those discussions with?

MS. MARTINEZ: Objection, privilege.

MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies.

MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer.

If you had a discussion with somebody in the outside that's not related to a policy decision like that, you can -- you can answer.

THE WITNESS: I can't answer.

BY MR. TORBORG:

Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct?

MS. MARTINEZ: Objection, form.

THE WITNESS: We did have those discussions.

BY MR. TORBORG:

Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct?

A. Correct.

Q. And did your discussions have any impact on the amount at which HCFA approved state Medicaid plans for payment of drugs?

A. I'm not sure I understand your question.

Q. Okay. Let me see if I understand.

We agree we had -- you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs.

MS. MARTINEZ: Objection, form.

BY MR. TORBORG:

Q. You had those discussions, right?

MS. MARTINEZ: Objection, form.

THE WITNESS: There were discussions.

BY MR. TORBORG:

Q. And in your office, you are responsible for determining whether or not to approve or disapprove state Medicaid plans in the -- at least in the area of prescription drug reimbursement, correct?

A. No, that's not correct.

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Q. This regional offices -- the regional offices had that responsibility?
A. It was a shared responsibility.
Q. Okay. And if I understand the basis for the insertion of privilege and your observation of the privilege is that those discussions related to some sort of policy, correct?
MR. HERNANDEZ: Objection to form.
MS. MARTINEZ: Decision -- decision by HCFA.
BY MR. TORBORG:
Q. A decision or a policy, correct?
A. A decision or a policy, correct.
Q. Okay. What decision or policy was that?
MS. MARTINEZ: Objection, form.
THE WITNESS: And, I'm sorry, I'm not sure what you're looking -- what you're --
BY MR. TORBORG:
Q. The deliberative process privilege is supposed to apply to deliberations leading to a

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decision or a policy.
A. Right.
Q. I'm trying to decide -- trying to figure out what decision or policy those discussions related to.
A. The decision would be how to look at this and reviewing a state plan.
Q. And whether or not to approve or disapprove the plan?
A. That could be part of that decision.
Q. Which would ultimately determine how much providers were paid for drugs, correct?
A. Correct.
Q. I'd like to ask you to go to the last page of the document -- second to last page and the last page, which are the letter response from the state of Minnesota to OIG's report.
MS. MARTINEZ: Montana?
MR. TORBORG: Come again?
MS. MARTINEZ: Montana?
MR. TORBORG: Montana report, yes, Bates 673, 674.

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Let me ask you, after you've had a chance to review those two pages, whether you recall this response from the state of Montana.
THE WITNESS: I don't recall this response.
BY MR. TORBORG:
Q. In the first paragraph, Montana's Peter Blouke -- I'm sure I'm not pronouncing that right -- indicated that, "Montana currently pays the lesser of AWP minus 10 percent, federal upper limit for multisource generic products. In addition to the product cost, Medicaid also reimburses a dispensing fee not to exceed $4.08 per script," then it continues.
And that's consistent, is it not, with the NPC report that I marked as Exhibit Abbott 326, the 1996 page?
MS. MARTINEZ: Sorry, are you -- is it Exhibit Abbott 327?
MR. TORBORG: Exhibit Abbott 326 is the NPC reports.
MS. MARTINEZ: Oh, right, right.

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THE WITNESS: The NPC 1996 report references AWP minus 10. It doesn't reference a federal upper limit price.
BY MR. TORBORG:
Q. Okay. The federal upper limit price was a -- was that a mandatory price?
MR. HERNANDEZ: Objection, form.
MS. MARTINEZ: Objection, form.
MR. TORBORG: Actually, strike that. That's probably not a very good way to ask that question. It doesn't matter.
And the NPC report also showed a dispensing fee of between $2 and $4.08, correct, which is consistent with the Montana letter?
MR. HERNANDEZ: Objection, form.
THE WITNESS: You're referring to the NPC 1996? I put it away, so I had to go back to it.
BY MR. TORBORG:
Q. Yes.
A. The dispensing fee is listed for Montana as $2 to 4.08.

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Q. Which is consistent with the letter, correct?
A. The letter indicates a dispensing fee not to exceed 4.08.
Q. So it's consistent, correct?
A. I can't --
MR. HERNANDEZ: Objection, form.
THE WITNESS: I can't -- they're different statements.
BY MR. TORBORG:
Q. Okay. This first paragraph also notes, "Montana's corresponding average discounts as computed by the OIG are 16.23 percent and 48.46 percent respectively."
Correct?
A. Correct.
Q. And then they note they currently are reimbursing the lesser of AWP minus 10 percent or the federal upper limit, correct?
A. Montana currently pays the lesser of AWP minus 10 percent -- that statement is correct.

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Q. And so there's quite a bit of difference between OIG's findings and Montana -- Montana's reimbursement methodology at that time, correct?
MS. MARTINEZ: Objection, form.
THE WITNESS: And clarify your question again. Are you referring to the set of drugs that the OIG looked at?
BY MR. TORBORG:
Q. I'm just comparing the Montana drug reimbursement methodology for ingredient cost with OIG's findings. They're inconsistent, are they not?
MS. MARTINEZ: Objection, form.
THE WITNESS: Again, this is a sample that the OIG did, and I don't know.
BY MR. TORBORG:
Q. Did you find OIG's work to be reliable in your work?
MS. MARTINEZ: Objection, form.
THE WITNESS: In some cases, we relied on it; in other cases, we did not.

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BY MR. TORBORG:
Q. For these specific reports, did you find OIG's work to be reliable?
MS. MARTINEZ: Objection, form.
THE WITNESS: I think these reports are directed more at the states, so I don't know that we needed to look at the reliability. These were directed at what the -- what the amounts were in individual states.
MR. TORBORG: We have to do a tape change.
THE VIDEOGRAPHER: This marks the end of Tape 3 of Volume II of the deposition of Larry Reed.
Going off the record. The time is 14:13:50.
(A break was taken.)
THE VIDEOGRAPHER: This marks the beginning of Tape 4 of Volume II of the deposition of Larry Reed.
Going back on the record. The time is 14:44:16.

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BY MR. TORBORG:
Q. Welcome back, Mr. Reed.
A. Thank you.
Q. I want to revisit some testimony we had during the last session.
You indicated there were some discussions within HCFA about the differences -- the greater difference in AWP acquisition cost for generic drugs versus branded drugs, correct?
MS. MARTINEZ: Objection to form.
THE WITNESS: That there was HCFA discussion of that? Yes.
BY MR. TORBORG:
Q. And I asked you about those discussions, counsel asserted the deliberative process privilege. I then asked you what policy or decision that those discussions related to, and your answer was the decision would be how to look at this in reviewing the state plans, and I asked whether or not to approve or disapprove the plans, and you answered that could be part of the decision.

EXHIBIT BO

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

VOLUME II

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.	:	CIVIL ACTION: 06-CV-11337-PBS

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA, Plaintiff, v. ABBOTT LABORATORIES, INC., et al., Defendants.	:	CASE NO. CV-05-219 JUDGE CHARLES PRICE

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conversations. It's just whatever sort of happened after we're in the production of the actual report.
Q. If you could look at the second page, it's an e-mail from Mary Beth Clarke to Robert Vito and Linda Ragone, Subject: Drugs, dated August 4, 1997.
Do you remember receiving this e-mail?
A. No.
Q. Who is Mary Beth Clarke?
A. Mary Beth Clarke was a program specialist in our office and then became head of the program evaluation division.
Q. Could you read Mary Beth Clarke's short e-mail to you?
A. I guess you guys already know the sad truth. The budget package contains a provision for reducing Medicare payments for prescription drugs to 95 percent of AWP. For some reason, this makes me feel worse than when it was AWP. What a futile attempt -- I can't wait to see if CBO even scored it for savings!
Q. What do you understand Mary Beth Clarke

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to be saying there?
A. That the new budget package set Medicare payments at 95 percent of AWP. She feels worse about that than when it was AWP.
Q. Do you have any idea why it was that Mary Beth Clarke felt worse about 95 percent of AWP than AWP?
MR. DRAYCOTT: Objection.
THE WITNESS: I do not know why. It might have been that it was still being based on AWP.
BY MR. COOK:
Q. Is it fair -- did you interpret Mary Beth Clarke to be saying, we thought AWP was too high, we showed them that AWP could be ten times acquisition cost, and Congress chose to discount it by 5 percent?
A. As I read it now?
Q. Yeah.
A. Because I don't remember. As I read it now, I think -- I take it to mean that they're still using AWP as the mechanism for reimbursement.
Q. And that was a sad truth, correct?

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A. A sad truth? I think she said it made her feel worse.
Q. In the first line: I guess you guys already know the sad truth. Right?
A. Yes, that's what she wrote.
Q. Were you disappointed that Congress reimbursed [sic] Medicare reimbursement by only 5 percent?
MR. DRAYCOTT: Objection.
THE WITNESS: I remember being happy that something had happened, and in our position, it -- that doesn't always happen. So I remember being happy that some change had been made. I'm not sure that -- I think I probably felt at the time that linking it to AWP may not be a good idea either. But I think it -- I believe -- I thought -- I remember being happy that something had happened.
BY MR. COOK:
Q. And when you heard -- did you review -- by the way, did you review the statute; did you read the statute when it came out?
A. I believe I did when it came out.

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Q. Okay. Did you understand Congress to be directing HCFA to pay 95 percent of the published AWP?
MR. DRAYCOTT: Objection.
THE WITNESS: I believe when I read that that -- well, I don't -- I don't have it in front of me, so I believe that it was supposed to be 95 percent of average wholesale price.
BY MR. COOK:
Q. And you understood that to be what is published in Red Book, Blue Book, Medispan, right?
A. That's what I took it to mean.
Q. Do you recall having any conversations with Mary Beth Clarke or Robert Vito about the legislation?
A. I don't remember them.
Q. If you could go back very quickly to, I don't have the exhibit number, I apologize, the very, very large document.
A. The big pile, yeah.
Q. That's Exhibit Abbott 089. Do you recall whether you passed on that underlying

EXHIBIT BP

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	CIVIL ACTION:
LITIGATION	)	01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
	)	Magistrate Judge
	)	Marianne B. Bowler

VIDEOTAPE 30(b)(6) DEPOSITION OF RENA L. CLARK, taken under and pursuant to the Federal Rules of Civil Procedure and the acts amended, and pursuant to Notice, before me, PHYLLIS M. KAPARIS, Registered Professional Reporter and Notary Public in and for the State of Wisconsin, at the law offices of Foley & Lardner, 150 East Gilman, Madison, Wisconsin, on February 8, 2008, commencing at 9:14 in the forenoon.

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Q. Okay. If I could direct your attention to the bottom of that page, 42 CFR Section 405.517, payment for drugs that are not paid on a cost or prospective basis.
A. Uh-huh.
Q. It goes over to the next page. Are you familiar with this regulation?
A. I'm not.
Q. This is not a regulation that you've reviewed before?
A. I may have, but it's not something I recall reviewing.
Q. Okay. Sorry. Lost my spot there. Under section (b), Methodology, the regulation states, Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as

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inventory, waste and spoilage.
As you -- as I read that to you today, in particular the terms national average wholesale price, what did you understand that to mean?
A. Average wholesale price as I know it to mean?
Q. Yes.
A. It's just what it says, an average wholesale price. It would be what a drug company -- the average of what the drug company charged entities who purchased the drug.
Q. Did CMS direct WPS where to look to obtain average wholesale price?
A. Yes.
Q. Where did CMS direct you to look?
A. There were a couple sources. The one we used most of the time was the Red Book drug topics.
Q. In your work at WPS has the term average wholesale price been synonymous with what -- the prices that would be contained in the Red Book or other price listings?
MR. HENDERSON: Objection.

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THE WITNESS: Yes.
BY MR. TORBORG:
Q. When you thought of AWP, you thought of Red Book; is that fair to say?
MR. HENDERSON: Objection.
THE WITNESS: That's true.
BY MR. TORBORG:
Q. I'll hand you what we've marked previously as Abbott Exhibit 38. Abbott 38 bears the Bates number HHD008-008 through 009. The first page is -- among other things, has some federal regulations on it. I'd like to ask you to go to the second page. And if you'd take a look at that to the extent necessary to let me know if you're familiar with that document.
A. No.
Q. Was there anywhere that WPS would look for guidance on Medicare reimbursement issues?
MR. HENDERSON: Do you have a time frame?
BY MR. TORBORG:
Q. Sure. From 1991 through 2001.
A. We would have used the Medicare Carriers

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Manual, and we would have used change requests and instructions, identical letters from CMS, or HCFA at the time.
Q. Does the second page of Abbott Exhibit 38 appear to be something out of a Medicare Carrier Manual, if you know?
A. I'm not sure. It could be. It's referring to, you know, different parts of the MCM, but I'm not sure if this is one or not.
Q. Under the Section 3421, Drugs, the second paragraph writes, Medicare pays for covered drugs at the lower of (1) the estimated acquisition cost of the drug or (2) the national average wholesale price of the drug (as published in the Red Book and similar price listings.) Is that consistent with how WPS used the term average wholesale price?
MR. HENDERSON: Objection.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. I'd like to show you another document we've marked also in this case. And this is Abbott

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Q. And someone has put some boxes around some of the various Vancomycin NDC's; is that fair to say?
A. Yes.
Q. Now, another one listed here is Vancocin, Lilly. Do you see the first one there is a 500-gram offering with a reported AWP of $7.80? Do you see that?
A. Under Vancocin?
Q. Yes, Vancocin.
A. Oh, yes. Okay.
Q. Then underneath it says Vancomycin hydrochloride?
A. Yes.
Q. Do you know why it is that WPS did not include the Lilly NDC in the array calculation?
A. It looks like it's a brand name.
Q. So you didn't include this because it was the brand name?
A. At that time, correct.
Q. Do you recall CMS directing you specifically not to include brand name in any

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conversation, apart from the memo we saw earlier?
A. I don't recall that, no.
Q. Do you recall any discussions about that, that issue of not being able to include brand named drugs in the array calculation?
A. I don't recall any specific discussions.
Q. If I can ask you to go to Bates Page 157. Are you there?
A. Yes.
Q. That was fast. The last paragraph on the page of this document which is a memorandum from Jim Cuca, it states the RO -- would that be regional office?
A. Yes.
Q. -- and appropriate carriers are currently investigating the price for Vancomycin, J3370. Does that refresh your recollection at all about any issues coming up with the price for Vancomycin?
A. I don't recall the specific issue. I remember that we had to provide the information to CMS as to how we calculated this.

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Q. Okay. If we go back to 157 -- or 155.
A. Okay.
Q. This is a file called 1996 Injections; is that right?
A. Yes.
Q. And I'd ask you to go to Page 172. This is a memo dated March 15, '96 from James Cuca. The last paragraph Mr. Cuca wrote, some of you have been approached by manufacturers complaining that their products' AWP's have been updated but are not reflected in the Red Book. Do you recall any -- ever being approached by a manufacturer relating to anything to do with AWP?
A. Yes.
Q. Okay. What do you recall about that?
A. We received letters from manufacturers on numerous occasions because we have to wait for the publication. That was just -- I don't know if that was a CMS policy or a WPS policy, but we always -- we wanted to have the Red Book publication in hand before we made changes. Until that was published and in hand, we didn't make

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changes, because you can't rely on data that you can't see.
Q. So if I understand correctly, in order for you to be able to use an AWP price, it has to specifically come from Red Book?
A. It doesn't have to specifically come from Red Book, but it has to specifically come from a published compendia. And a published compendia is something that's published that -- I guess it's not the manufacturer saying, we've raised the price; this is what our new Red Book amount is. It comes from the Red Book publication or Blue Book or Medispan or whatever.
Q. So if someone from Abbott had called you up and said, Ms. Clark, the AWP for Vancomycin, for example, should be $5, instead of what it was recorded in Red Book, could you use that?
A. No.
Q. And why is that?
A. Because it would not have been a published source.
Q. If you'll go to Page 168. Does this

Page 158

percent of the previous median AWP calculations; fair to say?
A. Correct.
Q. Go to 232 through 233. Does that appear to be a program memorandum from HCFA dated January of 1998?
A. Yes.
Q. And your office would received program memoranda from HCFA from time to time?
A. Yes.
Q. And this is discussing the impact of the Balanced Budget Act of '97; is that right?
A. Yes.
Q. If we go to the section, calculation of the AWP below, number two states, for a multi-source drug the AWP is equal to the median AWP of all the generic forms of the drug unless the brand name product AWP is priced below this median. If the brand name product AWP is lower than the median of the generic AWP's, calculate a new median with a brand AWP included. Do you see that?
A. Yes.

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Q. Is that consistent with your understanding of how WPS implemented the Balanced Budget Act of '97?
A. Yes.
Q. Let me ask you about the next document. Starting at Bates Page 235 to 236.
A. Okay.
Q. Is this another program memorandum from HCFA?
A. Yes.
Q. This one is dated December of '98; whereas, the one we just looked at was January of '98. Do you see that?
A. Yes.
Q. And if we look at Payments for Drugs and Biologicals, it states, Drugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as Red Book, Blue Book or Medispan. Do you see that?
A. Yes.
Q. Is that consistent with your

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understanding of what the law required carriers to do in calculating payments for drugs?
A. Yes.
Q. Okay. Is it your understanding that the law required that a carrier such as WPS use AWP prices found in published sources such as Red Book, Blue Book, or Medispan?
A. Yes.
Q. Go to number two under Calculation of the AWP. The memorandum states, For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all the generic forms of the drug or biological or the lowest brand name product AWP. A brand name product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.
Is that in any way different than the instruction you were given in the January, '98 program memoranda?
A. It's slightly different. In this version we would use the lower -- if the brand name

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was lower, we would use that as our fee. In the other one the brand name was incorporated into the array.
Q. And which one did WPS use in calculating its arrays, if you recall?
A. We used both of them. Because this one came -- this one was implemented, I believe, for the '97 pricing -- or '99 pricing. And this was used for pricing that was done through the year of '98.
Q. Okay. So in 1998 you would have included the brand into the median calculation?
A. Yes.
Q. If I could ask you to go to 180. I'm going to be skipping over one of the stacks that I gave you. I didn't find anything particularly interesting in that one.
A. Oh.
Q. So we'll go to July of 1998.
A. Okay.
Q. Are you with me?
A. Yes.

EXHIBIT BQ

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	)	MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	)	CIVIL ACTION
PRICE LITIGATION	)	01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)	
U.S. ex rel. Ven-a-Care of	)	Judge Patti B. Saris
the Florida Keys, Inc.	)	
v.	)	Chief Magistrate
Abbott Laboratories, Inc.,	)	Judge Marianne B.
No. 06-CV-11337-PBS	)	Bowler

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(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume I

Washington, D.C.

Thursday, January 24, 2008

9:00 a.m.

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Prescription Drugs.'" And it gives a number and a date.

In the first paragraph, Ven-A-Care wrote "As you may be aware, in September 1995 we met with representatives from the OIG and HCFA in Baltimore to discuss and present evidence of the fact that the Medicare and states' Medicaid programs were unwittingly making excessive reimbursements for certain infusion, injectable and inhalation drugs."

That's the meeting we saw earlier that looked like you attended; is that right?

MS. MARTINEZ: Object to form.

A. That meeting was in '95.

Q. It goes on, "During that meeting we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term 'AWP' had never been legislatively or administratively defined by the federal government."

Ms. Gaston, does that refresh your recollection at all regarding any conversation about that subject that occurred in the Baltimore meeting with Ven-A-Care in 1995?

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A. No.

Q. Do you recall that subject ever being discussed within HCFA, the fact that AWP, that term, had never been legislatively or administratively defined?

A. I don't recall.

Q. You don't recall any discussions about that issue?

A. I don't recall.

Q. And is that because it's been some time since both the September 1995 meeting as well as your time dealing with these issues?

MS. MARTINEZ: Objection, form.

A. It could be.

Q. If I could ask you to go to the next page. Ven-A-Care wrote "We contacted an official at the Bureau of Labor Statistics, Department of Commerce, whose branch of government also uses the words average wholesale price and the term AWP. When we asked if the Commence Department had ever defined the words 'average wholesale price" or the term 'AWP,' the official stated 'Mr. Bentley, I

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don't mean to be rude, but what is it exactly that you don't understand about the words average, wholesale, and price and/or the words average wholesale price put together as AWP?'" Do you see that?

A. Yes, I do.

MS. MARTINEZ: Objection, form.

Q. Do you recall there ever being any discussion of any issue within HCFA about what the term AWP meant?

MS. MARTINEZ: Objection, form.

A. Can you be more specific? Just what it means?

Q. Yeah.

A. There may have been discussions. I don't remember any specific discussions.

Q. Do you remember -- when you used the word or the phrase "average wholesale price," what did you understand it to mean?

MS. ALBEE: Objection, form.

A. Average wholesale price was a price that we used along with the direct price or the WAC price

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for determining the FULs. It really wasn't our place -- for me when I'm working on the FULs -- to get into defining it. I'm looking at it for FULs purposes.

Q. And where did you look to get average wholesale prices?

MS. MARTINEZ: Objection, form.

A. The three prices the average wholesale price, direct price and the wholesale acquisition cost, was provided to us by the compendia sources.

Q. That would be Blue Book, Red Book and Medi-Span?

A. Correct.

Q. And when you use the term average wholesale price and when you saw it used by others such as in state plans, that's what you understood the term to meant; is that right?

MS. MARTINEZ: Objection, form.

A. You mean to mean -- not defining it, but how I use it?

Q. Yeah. It meant what was in Blue Book, Red Book and other compendia?

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A. Yes.
Q. And did you understand that the average wholesale price for multiple source drugs in particular was not a reliable indicator of the cost at which pharmacies and physicians purchased drugs?
MS. MARTINEZ: Objection to form.
MS. ALBEE: Objection to the form.
MR. WINGET-HERNANDEZ: Objection, form.
A. As I stated before, my understanding is that I looked at average wholesale price, direct price, wholesale acquisition costs, the prices that were available in the compendia, and generally speaking the average wholesale price was a higher price at that point others.
Q. Did you have an understanding that the difference between average wholesale price published in the compendia and what people were buying the drugs for was particularly variable when it came to multiple source drugs as opposed to sole source drugs?
MR. WINGET-HERNANDEZ: Objection, form.
MS. ALBEE: Objection, form.

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MS. MARTINEZ: Objection, form.
A. I can't say that.
Q. Is that something that you were made aware of in multiple OIG reports?
MS. MARTINEZ: Objection, form.
A. It's mentioned in the OIG reports, yes.
Q. Let me ask you to look at page 685 of this document, the Bates page ending in 685. The last column, the first full paragraph starts with "stage agencies." Do you see that?
A. Yes.
Q. It says "State agencies should determine independent of the 150 percent formula appropriate payment levels for the listed multiple source drugs. We would not expect a state agency to adopt directly the upper limit methodology as a payment method because it does not gear payments to markups appropriate to the actual costs of acquiring and dispensing these drugs." Do you see that?
A. Yes, I do.
Q. Do you have an understanding of what that means?

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A. Just what they're saying.
Q. What are they saying?
A. So independently I guess states on their own shouldn't apply the 150 percent markup.
Q. If you go to the next paragraph, the second full sentence starts with "since." Do you see that?
A. No.
Q. "Since we are not placing" --
A. Where are you?
Q. The next paragraph down about eight lines down.
A. The next paragraph down?
Q. Yeah.
A. Okay. "Since we are not"? Okay.
Q. "Since we are not placing maximum payment limits on individual drugs, drugs with high compendia prices could generate extremely high payment levels. Unless an agency's payment methodology ensured otherwise, a Medicaid agency could end up paying inappropriately high rates for some drugs while still being in compliance with the

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aggregate upper limit.
"Nevertheless, we believe states may establish maximum payment limits in order to offset the minimum payment levels necessary to ensure reasonable compensation for very low priced drugs." Do you see that?
A. Yes.
Q. Do you have an understanding of what that last sentence means, establishing minimum payment levels necessary to ensure reasonable compensation for very low priced drugs?
A. Well, my understanding of what they're trying to say is that states have the flexibility to set a MAC on drugs that they feel are not priced appropriately.
Q. Do you know what they're talking about or how do you interpret the comment reasonable compensation for very low priced drugs?
A. That if they feel that the drug cannot be obtained in their state because the price is low, that they have the flexibility to set a MAC on a drug so that it will be obtainable within their